WORLD HEALTH ORGANIZATION
International Agency for Research on Cancer

Current Status and Future Directions of Breast and Cervical Cancer Prevention and Early Detection in Belarus

IARC 2012

WORLD HEALTH ORGANIZATION

INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

IARC

Working Group Report

Volume 6

CURRENT STATUS AND FUTURE DIRECTIONS OF BREAST AND CERVICAL CANCER PREVENTION AND EARLY DETECTION IN BELARUS

WHO/IARC

CANCER CONTROL ASSESSMENT AND ADVICE REQUESTED BY THE BELARUS MINISTRY OF HEALTH

REPORT OF EXPERT MISSION TO MINSK, BELARUS, 15–18 FEBRUARY 2011

Published by the International Agency for Research on Cancer
150 cours Albert Thomas, 69372 Lyon, Cedex 08, France

Distributed by WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int)

IARC Library Cataloguing in Publication Data

Current Status and Future Directions of Breast and Cervical Cancer Prevention and Early Detection in Belarus. WHO/IARC. Cancer Control Assessment and Advice Requested by the Belarus Ministry of Health. Report of Expert Mission to Minsk, Belarus, 15–18 February 2011. Editors, L. von Karsa, E. Suonio, T. Lignini, S. Ducarroz, A. Anttila

ISBN 978-92-832-2450-1

This report was compiled and edited by an IARC secretariat composed of L. von Karsa, E. Suonio, T. Lignini, S. Ducarroz and A. Anttila. In publications, it should be referred to as:

Current Status and Future Directions of Breast and Cervical Cancer Prevention and Early Detection in Belarus. WHO/IARC. Cancer Control Assessment and Advice Requested by the Belarus Ministry of Health. Report of Expert Mission to Minsk, Belarus, 15–18 February 2011, L. von Karsa, E. Suonio, T. Lignini, S. Ducarroz & A. Anttila, Editors. IARC, 2012.

Table of Contents

Annexes

Tables

WORKING GROUP PARTICIPANTS

Dr José Martin-Moreno
Director, Programme Management
WHO Regional Office for Europe
Copenhagen, Denmark

Dr Lawrence von Karsa
Head, Quality Assurance Group
Section of Early Detection and Prevention
International Agency for Research on Cancer
150 cours Albert Thomas
69008 Lyon, France

Dr Gunta Lazdane
Programme Manager
WHO Regional Office for Europe
Copenhagen, Denmark

Dr Eero Suonio
Visiting Scientist, Quality Assurance Group
Section of Early Detection and Prevention
International Agency for Research on Cancer
150 cours Albert Thomas
69008 Lyon, France

Dr Andreas Ullrich
Medical Officer Cancer Control
Department of Chronic Diseases and Health Promotion
WHO Headquarters
Geneva, Switzerland

Dr Ahti Anttila
Research Director of the Mass Screening Registry
Helsinki, Finland

Dr Egor Zaitsev
Head
WHO Country Office in Belarus
Minsk, Belarus

Professor Peter Dean
Radiologist and expert in breast cancer screening and diagnosis
Department of Diagnostic Radiology
University of Turku
Turku, Finland

Dr Valiantsin Rusovich
National Professional Officer, Communicable Diseases (tuberculosis)
WHO Country Office in Belarus
Minsk, Belarus

Ms Karin Jöns
Senior Adviser in European Social Policy Strategies
Member of the European Parliament 1994–2009
Brussels, Belgium

Dr Vera Ilyenkova
WHO Country Programme Coordinator, Communicable Diseases
WHO Country Office in Belarus
Minsk, Belarus

IARC Secretariat:
Dr Lawrence von Karsa
Dr Ahti Anttila
Mr Simon Ducarroz
Ms Maria Fernan
Ms Tracy Lignini
Dr Eero Suonio

Acknowledgements

Many people have contributed to this report, including, for example, the speakers and other dedicated staff who attended meetings and participated in discussions during the mission to Belarus. Their contributions, as well as those of the reviewers and editors, are gratefully acknowledged.

Preparation of this report was supported by the project entitled “European Cooperation on Development and Implementation of Cancer Screening and Prevention Guidelines (ECCG-ECN)”, grant agreement no. 2006322, which has received funding from the European Union in the framework of the Public Health Programme.

Co-funding was provided through the 2010–2011 Biennial Collaborative Agreement between the Ministry of Health of Belarus and the WHO Regional Office for Europe.

1 Executive summary

Mission aim

At the request of the Belarusian Minister of Health, a WHO/IARC expert mission was conducted in the city of Minsk and in the Minsk District from 15 to 18 February 2011. The purpose of the mission was to evaluate the current status of breast and cervical cancer prevention and early detection in Belarus and to develop recommendations for improvement.

The mission is relevant to the planning and implementation of new breast and cervical cancer screening programmes in Belarus and in countries with a similar health systems context.

Methods

The assessment was performed by a multidisciplinary team of WHO/IARC staff and external, internationally recognized experts in cancer control planning and health systems monitoring, and in implementation, quality assurance and evaluation of cancer screening programmes.

In the limited time available prior to and during the mission, the expert team examined the experience in early detection and screening of breast and cervical cancer in Belarus by analysing written reports and other information requested in advance from the national authorities; by visiting reference facilities involved in the current efforts for control and prevention of breast and cervical cancer that are designated to play key roles in the new breast and cervical cancer screening programmes currently being planned by the Ministry of Health; and through participation in a consensus and planning workshop organized by the Ministry of Health and the WHO Country Office in Belarus, with scientific support from IARC.

Consensus of national experts and WHO/IARC expert team

The workshop was attended by Belarus experts, senior staff of the Ministry of Health and the WHO/IARC expert team. The Belarus experts presented the results of approximately 40 years of a national programme of regular prophylactic examinations of the female population for breast and cervical cancer. Experience in the EU Member States in developing and implementing standards of best practice for breast and cervical cancer screening was also presented, and the applicability of this experience to the situation in Belarus was discussed. Subsequently, the attending national experts and the WHO/IARC experts agreed unanimously on key coordinates of the new Belarus screening programmes (Tables 6–9). The recommended coordinates build on the strengths of the previously established early detection programme and take into account the WHO recommendations on cancer screening [1; see also 3] and the more recently developed European standards for cancer screening [2–10] (see also Annexes A1–A4 and Appendix 1).

The Belarus experts and the WHO/IARC experts also agreed on the need for a comprehensive quality management programme based on the European standards. This will involve every step in the screening process, from identification and personal invitation of each individual in the eligible population, to performance of the screening test and multidisciplinary diagnosis and treatment of patients with lesions detected during screening. Quality standards in performance and in training, monitoring and evaluation, and effective communication enabling informed decisions are essential at each step in the process [2–10].

Programme management

In light of the current situation of breast and cervical cancer prevention and early detection in Belarus, in which opportunities but also complex risks exist, the most important recommendation that can be made at this time is to follow the quality-assured process of screening programme implementation that has been successful in the EU (Table 5). Planning followed by feasibility testing, piloting and phased rollout across the country will enable the

responsible authorities to control the implementation process and to verify, before substantial resources are consumed, that requisite changes to current practice will effectively minimize risks and maximize benefits.

In most EU countries, this process has taken 10 years or more, but the duration can be reduced through international exchange of experience and collaboration, which can be helpful to avoid common pitfalls encountered in other programmes.

Following the quality-assured process of screening programme implementation will provide the opportunity to test more effective screening modalities than those currently adopted in Belarus, such as primary HPV testing in women age 30 and above, and it provides the opportunity to begin screening in a restricted age range, with gradual expansion to the full age range when women are invited to the next screening round.

Adequate control of the process of screening programme implementation requires effective coordination of all activities, including quality assurance. Coordination is essential because the complexity of the multidisciplinary approach, the long duration of the implementation process and the potentially conflicting interests of the many organizations and individuals involved make it impossible to manage overall screening performance without effective coordination of all activities. Effective coordination requires an autonomous organization with managerial and budgetary control of programme activities.

Long-term political commitment and sustainable resources

Successful implementation of the new population-based cancer screening programmes will require long-term political commitment and sustainable resources. A key early task of the programme coordination will be the development of a comprehensive quality management programme that fulfils the standards in the European Guidelines. In a fully established screening programme, the proportion of expenditure devoted to quality assurance should be no less than 10–20%, depending on the scale of the programme. In the initial years, this proportion may be substantially higher due to the low volume of screening examinations compared with the situation after complete rollout of a nationwide programme.

Role of civil society

Quality-assured implementation of screening programmes also requires engagement of civil society throughout the process. Involvement of women's representatives and other stakeholders in the development of the programme will help to take the perspective of women into account in delivery of screening services and will enable these stakeholders to serve as multipliers in effectively communicating the benefits and risks of population-based screening. This should enable more women to make an informed choice about participating in screening.

Role of responsible authorities

The role of the responsible authorities should be to provide oversight, political support and adequate, sustainable resources for the programme, including particularly coordination and quality assurance. As recommended by WHO, these efforts should not be conducted in isolation, but integrated into an overall framework of comprehensive cancer control [16].

Action plan

A plan of action is proposed (Table 1; see also section 5.6) that takes into account the analysis of the current situation of breast and cervical cancer control in Belarus and the recommendations in this report. Consultation of competent independent experts is recommended throughout the process, particularly in developing and revising plans for feasibility testing, piloting and rollout, and in training, monitoring and evaluation. Given the

exemplary nature of the proposed activities, consideration could be given to seeking co-funding for programme development from external sources.

Table 1: Action plan for establishing population-based breast and cervical cancer screening in Belarus

1. Governance • Establish steering committee • Appoint responsible coordinator of breast and cervical cancer screening pilot programmes • Establish expert advisory board (include representatives of civil society) • Develop proposal for financing phases 2 and 3
2. Coordinator prepares workplans (for discussion with advisory board and approval by steering committee) • Feasibility testing • Piloting • Budgets • Organizational development (pilot leads, reference centres and other capacity for direct scientific and technical support)
3. Feasibility testing in small-scale studies • Screening modalities (invitation, testing, diagnostic work-up, treatment) • Quality assurance • Revision of workplans, depending on results
4. Initial workshops and other training for screening and other relevant staff (continuous process adapted to scale of programme activities)
5. Pilot testing (large-scale, “routine” setting) • Region with minimum of 500 000 general population • Two rounds of breast screening (2-year interval) • Similar time period (at least 5 years) for cervical screening • Screening modalities (invitation, testing, diagnostic work-up, treatment) • Monitoring and managing performance • Other aspects of quality assurance, including training • Reporting results • Revision of workplans, depending on results
6. Management and evaluation unit for the national programme • Establish organizational entity for monitoring and evaluation • Develop database for nationwide programme implementation • Develop infrastructure for nationwide delivery of personal invitations • Monitor results of the programme, and develop performance indicators • Develop quality criteria for phased rollout, and revise workplans accordingly
7. Countrywide rollout of the breast and cervical cancer screening programmes after elaborating the same issues (see 5 and 6) in programme management. • Phased rollout, beginning in a given region only after quality criteria are fulfilled • Monitor results of the programme, and develop performance indicators
8. Continuous quality improvement of programme based on • Performance monitoring and impact evaluation • International collaboration in quality assurance.

2 Introduction

The aim of screening as a tool for cancer control is to lower the burden of cancer in the population by discovering latent disease in its early stages and treating it more effectively than if diagnosed later, when symptoms have appeared. However, screening large segments of the population affects very large numbers of predominantly healthy individuals and should therefore only be conducted after careful consideration of both benefits and harms [3].

WHO and EU recommendations on cancer screening

WHO defined the first set of principles for population screening [1]. These principles are still valid today and are an integral part of the EU policy on cancer screening [2, 3] that is formulated in the 2003 Council Recommendation on Cancer Screening (Appendix 1). The EU policy provides a comprehensive framework for evidence-based decision-making and invites EU Member States to take common action to implement breast, cervical and colorectal cancer screening programmes with an organized, population-based approach and with appropriate quality assurance at all levels, taking into account European quality assurance guidelines for cancer screening.

Screening process

The special emphasis on quality assurance in cancer screening results in part from the experience in the EU in piloting and implementing nationwide screening programmes. This experience demonstrates that overall screening outcome must be measured at the end of the screening process. For the potential benefit of screening to be achieved, quality must therefore be optimal at each step in the process. This process includes identification and personal invitation of the target population,[1] performance of the screening test and, if necessary, diagnostic work-up, treatment and aftercare of screen-detected lesions. Quality standards in performance and in training, monitoring and evaluation, and effective communication enabling informed decisions are essential at each step in the process [3–11].

Importance of quality assurance

Screening is performed on predominantly healthy people; comprehensive quality assurance is also required to maintain an appropriate balance between benefit and harm in the large numbers of people eligible to participate in cancer screening programmes [3, 4, 11]. European quality assurance guidelines for breast (Annexes A1 and A2), cervical (Annexes A3 and A4) and colorectal cancer screening have been developed by experts and published by the EU [5–7; see also 8–10]. Supplements to the latest European Guidelines editions for breast and cervical cancer screening are currently being developed in projects coordinated by the Quality Assurance Group at IARC (European Cooperation on Development and Implementation of Cancer Screening and Prevention Guidelines [ECCG-ECN], http://www.iarc.fr/en/research-groups/QAS/current-topics.php).

Previous achievements in Belarus

Shortly after publication of the WHO recommendations on cancer screening in 1968, but decades before the development of the current European Guidelines, Belarus and a number of other European countries established national programmes for early detection of breast and cervical cancer. The Belarus programme has achieved a high volume of screening and a high degree of sustainability over the past 40 years. Currently, the burden of breast cancer in Belarus compares favourably with the situation in the neighbouring Baltic countries: the breast cancer mortality rate is 15.8 per 100 000 per year in Belarus versus 15.9, 17.6 and

[1] Target population: all women residing in the catchment area of a screening programme who are in the age group to whom screening is offered, as defined by the screening policy.

17.8 per 100 000 per year in Estonia, Latvia and Lithuania, respectively (world age-standardized rates) [12]. The situation with cervical cancer is similar. Only Latvia has a lower age-standardized incidence rate than Belarus, but the cervical cancer mortality rate is lower in Belarus than in the neighbouring Baltic countries: 4.9 per 100 000 per year in Belarus versus 6.2, 7.3 and 8.3 per 100 000 per year in Estonia, Latvia and Lithuania, respectively (world age-standardized rates) [12]. Undoubtedly the current burden of breast and cervical cancer in Belarus would be higher in the absence of the national early detection programme.

Despite this benefit, it should be recognized that the fundamental approach to early detection of breast and cervical cancer adopted in the current Belarus programme has been largely unchanged over the years and therefore does not take into account the more recent standards and recommendations for quality assurance and best practice on which the current EU policy on cancer screening is based (Annexes A1–A4 and Appendix 1).

New initiatives in Europe

Stimulated by the pan-European discussions leading up to and following the adoption of the Council Recommendation on Cancer Screening, several EU Member States have recently established population-based screening programmes for breast and/or cervical cancer, or have initiated a reorganization of previously existing non-population-based programmes [11, 13].

A similar initiative has recently been undertaken in Belarus, and in 2010 the Belarusian Minister of Health, Vasily Ivanovich Zharko, requested assistance from the WHO Regional Office for Europe in assessing the current approach to breast and cervical cancer control in Belarus and in developing recommendations for improvement. The results and conclusion of the requested assessment are relevant to the planning and implementation of new breast and cervical cancer screening programmes in Belarus and in countries with a similar health systems context.

3 Methods

WHO and IARC staff experienced in cancer control planning and health systems monitoring as well as in implementation, quality assurance and evaluation of cancer screening programmes established a multidisciplinary team that prepared and conducted a four-day mission to Belarus. Prior to the mission, comprehensive written information on the current status of breast and cervical cancer prevention and early detection was requested from the Belarus authorities; the WHO/IARC team collaborated closely with the national authorities and stakeholders to facilitate the compilation of the requested information. During the mission, key stakeholders were consulted and key reference facilities were visited that are likely to play major roles in the new breast and cervical cancer screening programmes that are currently being planned by the Belarus authorities. The information requested in advance from the national authorities and the site visits of the Belarus facilities were intended to provide a broad overview of current practices and policies of breast and cervical cancer prevention. Testing of equipment and in-depth review of test performance, diagnostic work-up and clinical management of screening clients or patients were not conducted.

In a workshop with the Belarus authorities and key stakeholders, the current results of breast and cervical cancer prevention and early detection in Belarus were presented by national experts. The IARC experts presented the state-of-the-art recommendations and guidelines of the EU for implementation and quality assurance of breast and cervical cancer screening programmes, as well as the extensive experience in the EU in successful implementation of population-based cancer screening programmes. A broad consensus between the national experts and the IARC experts on key recommendations for the breast and cervical cancer

screening programmes currently under development in Belarus was sought through a structured discussion moderated by the WHO experts.

Dr J. Martin-Moreno, Director of Programme Management in the WHO Regional Office for Europe, has taken the lead in responding to the request of the Belarusian Minister of Health. The focus of activities that are the subject of this report has been to assess the current status of breast and cervical cancer prevention and early detection in Belarus and to provide recommendations for improvement to the Ministry of Health. Dr G. Lazdane at the WHO Regional Office for Europe provided overall coordination of the mission preparation and follow-up. Dr E. Suonio coordinated the IARC scientific and technical contribution. Dr E. Zaitsev coordinated the activities of the WHO Country Office in Belarus.

3.1 Multidisciplinary team

At the outset, a multidisciplinary interdepartmental and interagency team (Table 2) was established involving the WHO Regional Office for Europe, the WHO Country Office in Belarus, WHO Headquarters and IARC. The Quality Assurance Group in the Section of Early Detection and Prevention at IARC, in concert with the WHO Regional Office for Europe, recruited additional experts in the fields of breast and cervical cancer screening and in the development of European health policy.

Table 2: Multidisciplinary WHO/IARC team

1.	Dr José Martin-Moreno, Director of Programme Management, WHO Regional Office for Europe, Copenhagen, Denmark
2.	Dr Ahti Anttila, Research Director of the Mass Screening Registry, Helsinki, Finland
3.	Professor Peter Dean, Radiologist and expert in breast cancer screening and diagnosis, Department of Diagnostic Radiology, University of Turku, Finland
4.	Dr Vera Ilyenkova, WHO Country Programme Coordinator, Communicable Diseases, WHO Country Office in Belarus, Minsk, Belarus
5.	Ms Karin Jöns, Senior Adviser in European Social Policy Strategies, Member of the European Parliament 1994–2009, Brussels, Belgium
6.	Dr Gunta Lazdane, Programme Manager, WHO Regional Office for Europe, Copenhagen, Denmark
7.	Dr Valiantsin Rusovich, National Professional Officer, Communicable Diseases (tuberculosis), WHO Country Office in Belarus, Minsk, Belarus
8.	Dr Eero Suonio, Visiting Scientist, Quality Assurance Group, IARC, Lyon, France
9.	Dr Andreas Ullrich, Medical Officer Cancer Control, Department of Chronic Diseases and Health Promotion, WHO Headquarters, Geneva, Switzerland
10.	Dr Lawrence von Karsa, Physician, Quality Assurance Group Head, IARC, Lyon, France
11.	Dr Egor Zaitsev, Head, WHO Country Office in Belarus, Minsk, Belarus

3.2 Audio conferences

The members of the multidisciplinary team listed above participated in audio conferences in November 2010 and January 2011 in which the scope and methodology of the WHO/IARC expert mission were discussed and refined.

3.3 Templates for assessing the current situation of cancer control in Belarus

Based on the discussion in the audio conferences, structured requests for background information on breast and cervical cancer control in Belarus were also developed and sent to the Belarus authorities:

- Template for cervical cancer, developed by Dr G. Lazdane in November 2010 (Annex A5);
- Template for breast cancer, developed by Dr E. Suonio in January 2011 (Annex A7).

Assistance to the Belarus authorities in dealing with the requests for information specified in the templates was provided by Dr E. Suonio at IARC by telephone and e-mail and by the WHO Regional Office for Europe.

In response to the templates, the Ministry of Health reported on the current programme of activities and results of cervical cancer prevention and early detection in Belarus in December 2010 (Annex A6), and in February 2011 additional background information was provided on control of breast and cervical cancer (Annexes A8–A13).

The detailed information provided by the Ministry of Health was used by the WHO/IARC multidisciplinary team to prepare a four-day expert mission to Minsk to assess the results of breast and cervical cancer prevention and early detection in Belarus, with special attention to the current approach to delivery of statutory prophylactic examinations to the adult population and the prospect of new programmes for breast and cervical cancer screening. The expert mission also provided an overview of capacity and preparedness of key reference facilities for implementation of the new breast and cervical cancer screening programmes currently being planned.

4 Evaluation

The evaluation of the information provided in the templates and the assessment of the current situation took place during the WHO/IARC expert mission to Belarus from 15 to 18 February 2011 in the city of Minsk and the Minsk District. The mission involved meetings with national officials at the Ministry of Health and with national experts, as well as inspections of oncological reference and training facilities and primary care facilities, including facilities for provision of services in the national programme of prophylactic examinations. The WHO/IARC team also participated in an expert workshop dealing with the performance and results of previous breast and cervical cancer control efforts in Belarus and the current plans for establishing new breast and cervical cancer screening programmes.

The experts who served on the WHO/IARC team that conducted the mission in Belarus are listed in Table 3.

Table 3: WHO/IARC expert mission team

1.	Professor Peter Dean, Radiologist and expert in breast cancer screening and diagnosis, Department of Diagnostic Radiology, University of Turku, Finland
2.	Ms Karin Jöns, Senior Adviser in European Social Policy Strategies, Member of the European Parliament 1994–2009, Brussels, Belgium
3.	Dr Valiantsin Rusovich, National Professional Officer, Communicable Diseases (tuberculosis), WHO Country Office in Belarus, Minsk, Belarus
4.	Dr Eero Suonio, Visiting Scientist, Quality Assurance Group, IARC, Lyon, France

5. Dr Lawrence von Karsa (IARC lead), Physician, Quality Assurance Group Head, IARC, Lyon, France
6. Dr Egor Zaitsev (WHO lead), Head, WHO Country Office in Belarus, Minsk, Belarus

4.1 Day 1 of the expert mission – Initial discussion with the Ministry of Health

On 15 February 2011, the IARC experts and the WHO experts on the mission team met at the WHO Country Office in Belarus to discuss the mission agenda. The mission aims and final agenda were agreed on in a subsequent meeting at the Ministry of Health with the following senior officials:

- Dr Valery Asimovich Hodjaev, First Deputy Minister of Health
- Dr Tatiana Fiodorovna Migal, Deputy Head of the Department of Health Services and Head of the Specialized Health Services Unit, Ministry of Health
- Mr Vladimir Vladimirovich Klimov, Head of the Foreign Relations Sector, Ministry of Health.

Plans for breast cancer screening are further developed

The Ministry officials also informed the WHO/IARC expert team that the current plans for breast cancer screening in Belarus are further developed than the plans for cervical cancer screening. Furthermore, initial steps are being taken to implement the breast cancer screening programme:

- The number of specialists in training has been increased.
- Mammography machines have been produced in Belarus since 2009.
- The Ministry of Health will purchase 28 new Belarus mammography machines in 2011.

Comments of the WHO/IARC expert team

The WHO/IARC expert team commented that the experience in the implementation of population-based breast cancer screening programmes as recommended by the Council of the EU has shown that it generally takes at least 10 years to fully establish a high-quality screening programme in a country. The implementation phase begins with extensive planning followed by small-scale scientific studies in which the feasibility of the screening approach foreseen for a country is tested. After the results of the feasibility testing are taken into account, piloting of the screening service on a larger scale can begin. Only when the results of pilot studies show that all steps in the screening process are functioning with high quality should rollout of the programme across the country begin.

Based on this experience, substantial investment in hardware would not be expected until after the piloting stage. However, improvements in diagnostic capacity prior to local implementation of the screening service can be helpful to avoid inappropriate waiting times. In the case of breast cancer screening, for example, such improvement may involve technical quality assurance of diagnostic mammography machines and other diagnostic equipment.

Mission schedule

The Ministry of Health suggested the following schedule for the mission, which was agreed on by the WHO/IARC expert team:

- 16 February 2011: Conduct site visits of current reference facilities in breast and cervical cancer control that are designated to play a leading role in the new breast and cervical cancer screening programmes:
    - N.N. Alexandrov Research Centre and Clinic for Oncology and Medical Radiology;

- Central District Polyclinic No. 34 of the Soviet District in Minsk.

- 17 February 2011: Assess the current status of breast and cervical cancer prevention and early detection in Belarus, and provide recommendations for improvement to the Ministry of Health:
  - Seminar on results of breast and cervical cancer control in Belarus;
  - Round-table discussion on key issues in future breast and cervical cancer screening programmes.

4.2 Day 2 of the expert mission – Site visits of key reference facilities

On 16 February 2011, the WHO/IARC team visited key reference facilities involved in planning and feasibility testing for the new breast and cervical cancer screening programmes that are currently being prepared in Belarus.

4.2.1 Alexandrov Research Centre and Clinic for Oncology and Medical Radiology

According to the information provided by the Belarus Ministry of Health, the N.N. Alexandrov Research Centre and Clinic for Oncology and Medical Radiology will serve as a national reference and training centre and will play a central role in the scientific, professional and organizational coordination of the future breast and cervical cancer screening programmes. The Centre collaborates with the Belarusian Medical Academy of Post-Graduate Education in the system of extended advanced training and certification of doctors, medical teachers, scientists and health personnel. The WHO/IARC expert team participated in the following meetings with senior staff and visited the following units within the Centre.

Meeting with Director, Dr Oleg Grigoryevich Sukonko

Dr Oleg Grigoryevich Sukonko, Centre Director, welcomed the WHO/IARC expert team and introduced key Centre staff involved in the preparations for the future breast and cervical cancer screening programmes (Table 4).[2] Dr Sukonko explained and agreed to the detailed agenda for the subsequent visits to the individual units in the Centre with the WHO/IARC team.

Table 4: Senior staff introduced during the visit to the Alexandrov Research Centre and Clinic for Oncology and Medical Radiology

1.	Dr Sergey Anatolievich Krasnyi, Deputy Director for Research
2.	Dr Natalia Nikolaevna Antonenkova, Deputy Director of Organization and Methodological Studies
3.	Dr Nina Nikolaevna Antonenkova, Chief Research Associate, Department of Oncomammology
4.	Dr Yuri Ivanovich Averkin, Head, Department of Cancer Epidemiology
5.	Dr Oksana Alekseevna Erokhina, Physician-Cytologist, Chief Supernumerary Specialist on Cytology, Ministry of Health; Secretary of the Belarus Association of Clinical Cytologists
6.	Dr Andrei Georgievich Ilkevich, Physician, Department of Radiation Diagnostics
7.	Dr Galina Vladimirovna Kostevich, Scientific Worker, Oncologist, Obstetrician-Gynaecologist
8.	Dr Tatiana Anatolievna Kuznetsova, Physician, Department of Radiation Diagnostics
9.	Dr Tatiana Mikhailovna Litvinova, Chief Research Associate, Department of Oncogynaecological Pathology

[2] Table 4 does not include the names of all the specialists who were interviewed during the visits to the individual clinics. It includes only the staff who attended the introductory meeting and participated in the concluding discussion.

10. Dr Pavel Ivanovich Moiseev, Head, Department for Organization of Cancer Control and International Cooperation
11. Dr Tatiana Ivanovna Nabebina, Physician-Pathologist
12. Professor Leonid Alekseevich Putyrski, Head, Department of Oncomammology

Visit to Breast Cancer Unit, led by Dr Nina Nikolaevna Antonenkova, Chief Research Associate of the Department of Oncomammology

- The unit has 85 beds in 2 wards and performs 16–20 breast cancer operations per week. With the current capacity, it is possible to perform 3 operations in each of 3 operating theatres on each of 4 operating days, for a total of 36 operations per week.
- All mammography machines are digital. Film mammography was discontinued 2 years ago. The machine used is the Siemens Mammomat 3000 (2005).
- Stereotactic core biopsies[3] are performed; vacuum-assisted biopsies are not performed.

Visit to Department of Histopathology, led by Dr Oksana Alekseevna Erokhina, Physician-Cytologist, Chief Supernumerary Specialist on Cytology, Ministry of Health

- Meeting with the Director of the Republican Centre of Clinical Cytology, Professor Ludmila Borisovna Klukina.
- Pappenheim staining is used for cervical smears; 70% of all smears come from outpatient rapid diagnostics; an HPV PCR laboratory is established; there is no computerized registry for cytology.
- Meeting with the Head of the Department of Histopathology, Dr Alexander Cheslavovich Dubrovsky.
- HER2 and ER/PR receptor status is routinely determined for breast cancers; large-section histology is not practised with breast cancer specimens, and neither is specimen X-ray; the histopathologist's report is predominantly unstructured (not a pro forma).

Conclusions by Dr Sergey Anatolievich Krasnyi, Deputy Director for Research

- Registration will be a major obstacle for a new cervical cancer screening programme.
- For breast cancer screening based on mammography:
  - Mammography machines are available, and more have been ordered.
  - There is currently a shortage of radiologists.
  - There are enough breast surgeons for the current number of breast cancer patients.
  - There will be a shortage of pathologists.
- A breast cancer screening pilot study has been planned. It would be carried out in three areas, for 90% of women aged 50–69 years, by individual invitation, every 2 years, with a TV and radio campaign. Two regions have already been selected:
  - Zhodzina, a town in the Minsk Region, 50 km north-east of Minsk. It covers an area of 19 km^2 and has a population of 61 800.
  - Maryina Horka, a town in the Minsk Region, 60 km south-east of Minsk. It is the capital of the Pukhavichy District. As of 2009, its population was 22 500.

[3] Core biopsy: a percutaneous biopsy using a cutting needle to provide a core of tissue for histological assessment without an operation. Vacuum-assisted biopsies are also included in this category.

Comments of Dr L. von Karsa, Head of IARC Quality Assurance Group

- A number of countries in Europe have been in a situation similar to that of the Alexandrov Research Centre at the outset of efforts to establish high-quality breast and cervical cancer screening programmes. The challenges of setting up a population-based screening programme that fulfils the high standards in the European Guidelines may seem daunting due to the complexity of the screening process (which begins with identification and personal invitation of the eligible target population, and includes performance of the screening test, diagnostic work-up of participants with abnormal test results and, in some cases, treatment and aftercare). However, the same overarching issues of quality assurance apply in any country, such as coordination, communication, registration, monitoring and evaluation, and Belarus can benefit from the lessons learned elsewhere in Europe in implementation of the European Guidelines. Furthermore, the process of setting up a programme can be standardized. The approach that has been successful in the EU begins with planning, followed by feasibility testing, piloting and phased, quality-assured rollout across a country or region (Table 5, [14; see also 15]). The implementation process lends itself to a step-by-step approach and in many countries takes at least 10 years. From the beginning there is substantial added value in terms of improvements in protocols and procedures for symptomatic disease, due to the need to optimize diagnosis and management of early-stage disease in the planning and piloting stages of programme implementation.
- A future programme coordinator can be confident that the problems that are encountered can be solved, if he or she insists that adequate resources are provided to effectively manage the implementation process. Adequate time for each stage in the process and adequate resources for international cooperation and collaboration in quality assurance are essential.
- If external resources are provided, IARC could assist in the provision of training and technical quality assurance to the N.N. Alexandrov Research Centre. This can be through collaboration in studies and projects, through recruitment of experts in the European Cancer Network into which the former EU cancer screening networks have been consolidated and through recruitment of a collaborating training and reference centre or centres.
- With regard to the mass media campaign planned for the breast pilot projects mentioned above, previous experience shows that it is necessary to be cautious when advertising screening to the general public, as it tends to rapidly flood the capacity.

Table 5: Sequence of steps in quality-assured implementation of screening programmes[a]

1.	Comprehensive **planning** of screening process: feasibility of screening models, professional performance, organization and financing, quality assurance.
2.	Preparation of all components of screening process to perform at requisite high level (including **feasibility testing**).
3.	Expert **verification** of adequacy **of preparations**.
4.	**Piloting** and modification, if necessary, of all screening systems and components, including quality assurance, in routine settings.
5.	Expert **verification** of adequacy **of pilot performance**.
6.	Transition of pilot to service screening and geographically phased **programme rollout** in other regions of the country.
7.	Intensive **monitoring of programme rollout** for early detection and correction of quality problems.

[a] Ref. 14.

4.2.2 Central District Polyclinic No. 34 of the Soviet District in Minsk

Meeting with Chief Physician, Dr Dmitri Evgenievich Shevtsov, and tour of the polyclinic

In addition to his responsibilities as Chief Physician of the polyclinic, Dr D. Shevtsov is also a member of the Minsk City Council and the President of the Belarusian Association of Physicians.[4]

The polyclinic serves a population base of 40 500 people (34% of pension age, i.e. 55 years and older for women, 60 years and older for men). It includes 2 paediatric polyclinics, 2 adult polyclinics, 1 polyclinic for students and 2 dental polyclinics. There are 230 staff, including 72 physicians, a few of whom are specialists (e.g. gynaecologists, an oncologist, urologist, neurologist and ophthalmologist). The oncologist's post is currently vacant.

Staff also includes paramedics ("physician aides") functioning on a level between a doctor and a nurse, i.e. they are supervised by a physician and assisted by nurses. Physician aides perform primary triage of patients. For example, they have the right to prescribe medicines but do not have the right to sign sick leave certificates.

- **Current practice of cervical cancer screening in the framework of prophylactic examinations**

At the polyclinic, midwives and gynaecologists carry out annual prophylactic examinations of women. These include full inspection of skin and genitalia; palpation of thyroid, breasts and superficial lymph node areas; rectal examination from age 40 years; cervical cytological smear with Pappenheim[5] staining. The stained slides are sent for analysis to the nearby Minsk City Oncological Dispensary. Women with ASC-US/LSIL are considered to be at elevated risk of cervical cancer and require follow-up. Cytological samples are obtained from practically all women above 40 years of age more often than once a year. Treatment of cervical lesions is carried out in the nearby Minsk City Oncological Dispensary, which also performs the early follow-up.

Of the 22 500 women that the polyclinic serves, 50% are of child-bearing age and 86% are screened annually.

There are 4 gynaecologists, and each sees 25–30 patients per day. The official norm is 12 minutes per patient, and 42% of the women are above 60 years of age.

There are plans to develop a centralized digital archive for pathology (cytopathology and histopathology) services.

- **Breast cancer screening**

There is a new mammography X-ray machine, a Belarusian ADANI Mammoscan (2010), that was just being installed at the polyclinic and was expected to be in use in March 2011. Similar machines were installed in seven other polyclinics in Minsk during 2009 and 2010. The mammography services are referred to as interdistrict mammography offices, serving the population of more than one district.

The Mammoscan machine was said to have a CE certificate, but documentation was not available during the visit. The following basic parameters were communicated to the

[4] Note: the Association of Physicians is not the national trade union to which most physicians belong.

[5] The Pappenheim staining method is not the method recommended by the European Guidelines for cervical cytology (the Papanicolaou staining method; see [6]). No validation study results were presented to the WHO/IARC team during the mission.

WHO/IARC expert team: maximum image size of 22 × 28 cm; 54 µm pixel size reaching 10 line pairs/mm in standard resolution mode. The workstation is from Planar Dome.

The price of a Mammoscan was said to be about €120 000.

A vacancy for a radiology nurse is being advertised on Polyclinic No. 34's web site. The price of a mammography examination is not yet included in the web site price list.

- **Discussion with the WHO/IARC expert team**

The potential was acknowledged of building on the strengths of the polyclinic infrastructure and the high acceptance of the female population for the statutory prophylactic examinations in establishing population-based breast and cervical cancer screening programmes. Continued training of existing staff and reorganization of existing services appears to be an option of greater relevance to the new cervical screening programme than to the new breast screening programme. The latter will require recruitment of radiographers and radiologists and their integration into a multidisciplinary screening service. Conversion to the Papanicolaou staining method and reduction of the number of screening tests in a woman's lifetime would likely improve the effectiveness and the cost-effectiveness of the screening programme and would help to reduce the risk of negative side effects of screening, which adds up over time.

4.3 Day 3 of the expert mission – Seminar and round-table discussion with national experts and authorities

The third day of the mission was devoted entirely to reporting by the national authorities and experts on the current results of breast and cervical cancer control in Belarus, and on developing consensus on an evidence-based approach to future improvement through implementation of European Recommendations and Guidelines for best practice and quality assurance in cancer screening. The reports and discussions were conducted in the frame-work of a seminar with scientific presentations, followed by a round-table discussion of previously agreed topics as well as questions resulting from the preceding presentations. In the concluding session, key mutually agreed recommendations of the national experts were developed, based on the results of the round-table discussion with the WHO/IARC experts. The agenda of the day's meetings with the list of participants is provided in Annex A14.

4.3.1 Seminar on results of breast and cervical cancer control in Belarus and European experience in development and implementation of cancer screening standards and guidelines

Dr T.F. Migal opened the seminar with an overview of the health care system in Belarus and the main current problems and questions (Annex A15). A highly developed health care infrastructure is established, with 3 clinicians and 7 mid-level medical personnel per 1 000 inhabitants. Among other things, the need for external assistance in training multidisciplinary teams for cancer screening, diagnosis and therapy was highlighted.

Professor L.A. Putyrski presented the extensive previous efforts and the results to date of breast cancer prevention and early detection in Belarus based on breast self-examination and clinical examination (Annex A16). At best, only a modest impact on the burden of disease is discernible. Professor Putyrski confirmed that according to current plans, the new breast cancer screening programme should start in Minsk and the Minsk Region.

Dr T.M. Litvinova presented the current burden of cervical cancer in Belarus (Annex A17). The age-standardized rate of invasive cervical cancer (12.7 cases per 100 000) is higher than the rates in many EU countries and leaves considerable room for improvement, given the long history of cervical cancer prevention in Belarus (more than 30 years) and the high volume of screening examinations (currently 3.6 million cervical samples per year). The

burden of disease is significantly higher in rural areas (17.3 cases per 100 000) than in urban areas (11.3 cases per 100 000). Treatment methods for precancerous lesions include photodynamic therapy, but it is unclear whether this approach will effectively lower the HPV viral load.

Professor L.B. Klukina and Dr O.A. Erokhina reported on the extensive cytological practice in Belarus (Annex A18).

- There are 37 central cytological laboratories; 25 of them process cytology samples from prophylactic examinations.
- In 2009, 88% of all women nationwide were examined. This figure is not compiled from individual data, and because many women had more than one smear, the actual percentage is lower.
- During the past 10 years, the annual incidence (absolute numbers) of invasive cancers has been relatively stable (843 to 893 cases per year), whereas during the same period the incidence of carcinoma in situ has risen from 191 to 868.
- During the past 30 years, the percentage of stage I cancers has increased from 15% to 37% in patients with newly diagnosed invasive cervical cancer. The percentage of stage IV cancers is largely unchanged (5.8% in 1978 and 6.4% in 2009).
- The presenters pointed out that a screening registry is needed. They recommended that cytology should be performed every 3 years and in accordance with the European Guidelines.

Dr L. von Karsa reported on the EU policy on cancer screening (Recommendation of the Council of the EU to the EU Member States on cancer screening, and the European guidelines for quality assurance of breast and cervical cancer screening) and the wide implementation of this policy in the EU (Annex A19).

He explained the paramount need for high quality at every step of the screening process, beginning with identification and invitation of the target population and including performance of the screening test, diagnostic work-up of lesions detected in screening and, if necessary, treatment and aftercare. Recognition of the primary importance of high quality in cancer screening was a key reason for adoption of the Council Recommendation.

He also explained the importance of a population-based approach to implementation of cancer screening programmes, which is also fundamental to the Council Recommendation on Cancer Screening. The population-based approach aims to give each eligible person an equal chance of benefiting from early detection of cancer, and it provides the organizational framework for comprehensive quality assurance at every step in the screening process.

He repeated for the larger group of participants attending the seminar the above-mentioned importance of adhering to the long-term process of planning, feasibility testing, piloting and phased, quality-assured rollout of population-based screening programmes (Table 5). Following the example set by EU countries that have successfully implemented population-based cancer screening programmes can be helpful to avoid setbacks and delays resulting from inadequate preparations throughout this lengthy process.

He also pointed out that quality-assured implementation of population-based cancer screening programmes improves the overall level of cancer care in a country because large numbers of professionals train to meet the high screening standards. These professionals are generally also involved in diagnosis and treatment of symptomatic disease.

In an oral statement, former Member of the European Parliament Karin Jöns pointed out the importance of continuously striving to improve quality and performance in cancer screening, diagnosis and therapy. This has been equally important throughout the EU, even in those Member States with highly developed health care systems. A case in point is the project slated to begin soon to pilot an accreditation scheme for breast cancer units. This project will

help to reduce unnecessary disparities in the EU with respect to the proportion of women who receive breast-conserving treatment for small breast lesions.

Professor P. Dean reported on major issues associated with introduction of nationwide mammography screening (Annex A20). He highlighted the importance of:

- a target age range to 50–69 years, initially;
- a 2-year screening interval;
- independent double reading of all screening mammograms;
- evaluation of all recalled women by the screening radiologists;
- interdisciplinary pre- and post-operative conferences involving pathologists, radiologists, surgeons, oncologists, radiographers and breast nurses;
- specimen radiography (X-ray of surgical specimens) to assist the pathologist in determining full tumour extent and margins;
- increasing diagnostic imaging capacity prior to introducing screening in a region (mammography, ultrasound, image-guided core needle biopsy and breast MRI);
- training radiologists to specialize in breast screening;
- quality control, such as checking previous films of all detected cancers, investigating reasons for any delay and identifying the cause of any unclear margin;
- teamwork, with good communication between all members of the team;
- learning how to screen from an experienced teacher (the radiologist must review the pathology of the patients sent to surgery, and review the mammograms of any cancers that have been missed).

Dr E. Suonio reported on key principles and recommendations in the current, second edition of the European cervical cancer screening guidelines (Annex A21). He emphasized the importance of:

- reporting the key organizational parameters determining the population base, such as details of the invitation policy, including whether women are sent invitation letters with a pre-fixed, modifiable appointment;
- recording diagnostic protocols;
- reminding all non-compliers with screening, or follow-up of positive tests;
- collecting evidence of programme effectiveness, based on reduction of incidence and mortality and using surrogate indicators.

4.3.2 Round-table discussion on key issues in future breast and cervical cancer screening programmes

With the exception of Dr T.F. Migal, all of the experts who participated in the morning seminar also took part in the round-table discussion. The questions and discussion focused on the key issues that would have to be resolved in order to achieve consensus on an evidence-based approach to breast and cervical cancer screening that could fulfil the fundamental criteria of the Council Recommendation on Cancer Screening and the European Quality Assurance Guidelines.

The questions on cervical cancer screening focused on:

- the need for a population-based programme
- the screening age range

- the screening interval
- the role of colposcopy in screening
- the staining method
- the classification system.

Consensus among the national experts was reached on key coordinates of a new cervical cancer screening programme (Table 6).

The WHO/IARC experts confirmed the conformity of these criteria with the European standards.

Table 6: Key coordinates of a new cervical cancer screening programme

• A population-based programme organization with individual invitation and individual data for quality assurance is recommended.
• All 30–60-year-old women should be personally invited every 5 years to attend screening.
• Colposcopy should be used only as a diagnostic procedure, not as a screening test.
• The Papanicolaou staining method should be used.
• The Bethesda system should be used to report cytology results for follow-up.

The questions on breast cancer screening focused on:

- the screening age range
- the screening interval
- digital mammography and the importance of technical quality assurance
- the mammography views
- the multidisciplinary approach throughout the screening process, including diagnosis and therapy
- centralized assessment in which the same diagnostic specialist performs all necessary diagnostic examinations (reading mammograms, ultrasound, breast biopsy and preoperative MRI).

Consensus among the national experts was reached on key coordinates of a new breast cancer screening programme (Table 7).

The WHO/IARC experts confirmed the conformity of these criteria with the European standards.

Table 7: Key coordinates of a new breast cancer screening programme

• A population-based programme organization with individual invitation and individual data for quality assurance is recommended.
• All 50–69-year-old women should be personally invited every 2 years to attend screening.
• Digital mammography should be used. Special attention must be paid to technical quality assurance.
• Two views should be used: craniocaudal and mediolateral oblique.
• A multidisciplinary approach is required throughout the screening process, including diagnosis and therapy.

- Centralized assessment is required in which the same diagnostic specialist performs all necessary diagnostic examinations (reading mammograms, ultrasound, breast biopsy and preoperative MRI).

Consensus on the need for comprehensive quality assurance

- The Belarus experts and the WHO/IARC experts also agreed on the need for development of a comprehensive quality management programme based on the European Guidelines. This will involve every step in the screening process, from identification and personal invitation of each individual in the eligible population, to performance of the screening test and multidisciplinary diagnosis and treatment of patients with lesions detected during screening. Overarching issues of quality assurance such as coordination, communication, registration, monitoring and evaluation must also be considered.
- The national experts attending the workshop also acknowledged the need to effectively develop and implement such a quality management programme in an objective manner, taking into account the quality-assured process of screening programme implementation that has been successful in the EU (see Table 5 and additional recommendations below).
- The WHO/IARC experts and the national experts jointly emphasized the importance of not merely assuring the quality of service provision in a new screening programme but also assuring the quality of the process by which a new programme is established. Tables 8 and 9 illustrate this important point. They show substantial differences between the activities in the current programme of prophylactic examinations in Belarus and the proposed future programmes of breast and cervical cancer screening. Given the high acceptance of women of the national programme of prophylactic examinations, there was unanimous agreement between the national experts and the WHO/IARC expert team that abrupt changes affecting the very large number of women and the large number of health professionals involved in the provision of prophylactic examinations should be avoided. Instead, the transition phase from prophylactic testing to population-based screening for breast and cervical cancer should be carefully planned and carried out. This will not only help to avoid unnecessary duplication of effort and other potential inefficiencies but will also facilitate efforts of the dedicated professionals and other staff providing future prophylactic examinations for other reasons to motivate women to attend the new population-based cancer screening programmes.

Additional recommendations of the WHO/IARC team

- The WHO/IARC expert team explained that quality-assured implementation of screening programmes requires an autonomous organization with a dedicated budget and personnel. Early appointment of a competent programme coordinator is essential. The coordinator must be equipped with the mandate and the resources to effectively manage the entire implementation process, beginning with planning and followed by feasibility testing and piloting and subsequent phased rollout of the programme across the entire country.
- In most EU countries this process has taken 10 years or more, but the duration can be reduced through international exchange of experience and collaboration in quality assurance. The results of this WHO/IARC expert mission should be taken into account in the further planning of the new Belarus screening programmes before feasibility testing and piloting begins.

Long-term political commitment and sustainable resources for coordination

- The WHO/IARC expert team also emphasized that successful implementation of the new population-based cancer screening programmes will require long-term political commitment and sustainable resources.

- This is illustrated by the key early task of the programme coordination to develop a comprehensive quality management programme that fulfils the standards in the European Guidelines. This requires an autonomous organizational status with a dedicated, sustainable budget and managerial and budgetary control over programme activities.
- In a fully established programme, the proportion of programme expenditure devoted to quality assurance should be no less than 10–20%, depending on the scale of the programme. In the initial years, this proportion may be substantially higher due to the low volume of screening examinations compared with the situation after complete rollout of a nationwide programme.

Engagement of civil society

- The WHO/IARC expert team also explained that quality-assured implementation of screening programmes requires engagement of civil society throughout the process. Involvement of women's representatives and other stakeholders in the development of the programme will help to take the perspective of women into account in delivery of screening services. Discussion of the rationale for changing the programme of prophylactic examinations in order to improve control of breast and cervical cancer, and discussion of the results of feasibility studies and pilot studies with women and other stakeholders will also enable these stakeholders to serve as multipliers in effectively communicating the benefits and risks of population-based screening. This should enable more women to make an informed choice about participating in screening.

National reference and training centre

- The WHO/IARC expert team also emphasized the need for the coordination team to monitor all screening activities and to work closely with a national reference and training centre and the national authorities and other institutions that will play key roles in the delivery of the screening services, such as primary care facilities and the cancer registry.
- The reference facilities visited by the WHO/IARC expert team, particularly the N.N. Alexandrov Research Centre, have the potential to develop into national reference and training centres for breast and/or cervical cancer screening, provided that adequate and sustainable resources are made available.
- If the competence of the reference centre is demonstrated in the pilot phase, the national reference centre could also serve as a training centre for neighbouring countries.

Table 8: Screening for cervical cancer. Comparison of the current situation with key coordinates of a future model based on current consensus with national specialists

Current practice	Future model towards conformity with internationally recognized European standards
Cervical cytological sample obtained opportunistically, without personal, population-based invitation	Personal invitation of all eligible women to attend cervical screening
No upper age limit for eligibility. Effective age range is currently 18–100 years	Eligible age limited to 30–60 years
The Pappenheim method (May-Grünwald-Giemsa) – not the Papanicolaou method – is used for cytological staining	The Papanicolaou method, recommended by the European Guidelines, to be used for cytological staining
Cytological sampling recommended annually	Five-year interval for quality-assured screening
Follow-up not standardized according to the	Cytology results to be reported according to, and follow-

cytological findings	up protocols to be based on, the Bethesda system

Table 9: Screening for breast cancer. Comparison of the current situation with key coordinates of a future model based on current consensus with national specialists

Current practice	Future model towards conformity with internationally recognized European standards
Prophylactic testing (clinical breast examination) performed by primary health care staff	Available evidence supports only screening by mammography
Breast self-examination encouraged	In the interval between screening mammography, breast awareness and self-examination recommended, with consultation of medical services if lumps or other symptoms are noticed
Population-based screening with mammography not currently used	Personal invitation of all eligible women to population-based screening programme based on mammography
Eligible age range undefined	Eligible age limited initially to 50–69 years
Examination interval undefined	Two-year interval for quality-assured screening
Women are uninformed about mammography	High-quality information about breast screening and mammography to be provided with the invitation
Single specialist determines diagnosis without systematic quality checks	Independent, supervised reading of all mammograms by two specialists
	Multidisciplinary diagnosis with pre- and post-operative conferences
	Fail-safe mechanisms, check protocols and linkage to other registers for effective monitoring and quality assurance of each step in screening process, including invitation
	Mammography performed in two projections (mediolateral oblique and craniocaudal)

4.4 Day 4 of the expert mission – Final discussion with the Ministry of Health

The preliminary results of the mission were presented to the First Deputy Minister of Health, Dr Valery Asimovich Hodjaev, at a meeting at the Ministry of Health on 18 February 2011. The following people attended the meeting:

- Dr Valery Asimovich Hodjaev, First Deputy Minister of Health
- Dr Tatiana Fiodorovna Migal, Deputy Head of the Department of Health Services and Head of the Specialized Health Services Unit, Ministry of Health
- Dr Egor Zaitsev (WHO lead), Head, WHO Country Office in Belarus, Minsk, Belarus
- Dr Lawrence von Karsa (IARC lead), Physician, Quality Assurance Group Head, IARC, Lyon, France
- Professor Peter Dean, Department of Diagnostic Radiology, University of Turku, Finland

- Ms Karin Jöns, Senior Adviser in European Social Policy Strategies, Member of the European Parliament 1994–2009, Brussels, Belgium.

In the summary presentation, the WHO/IARC team highlighted the following points:

1) The current approach to early detection of breast and cervical cancer in Belarus could be improved by implementation of population-based screening programmes that fulfil the quality criteria recommended by the EU.
2) The clinical and organizational coordinates of the new screening programmes will differ considerably from the approach in the existing national programme of prophylactic examinations (see Tables 8 and 9).
3) Despite the potential for improvement, the current situation also reveals important strengths, which are lacking in a number of other countries currently seeking to improve control of breast and cervical cancer (for details, see section 5).
4) The main weakness revealed by the mission in the current context is the lack of experience in the quality-assured process of implementation of population-based screening programmes, which generally takes 10 years or more from the beginning of programme planning to the completion of feasibility testing, piloting and phased rollout across a country (for more details, see section 5).
5) A plan of action was discussed that encompassed the following points:
    a) governance
    b) coordination (organizational, technical and scientific)
    c) feasibility testing in small-scale studies
    d) training
    e) pilot testing (large-scale, “routine” setting)
    f) monitoring and evaluation unit for the national programme
    g) countrywide rollout.
6) Significant, sustainable resources would be required to implement the action plan, including resources for international cooperation and collaboration. Due to the exemplary character of the proposed activities, consideration could be given to potential sources of external co-funding.

The First Deputy Minister of Health, Dr Valery Asimovich Hodjaev, thanked the WHO/IARC expert team for the mission and suggested that piloting should begin in Minsk. The WHO/IARC experts agreed that the city of Minsk would be suitable for implementation of the first pilot project, provided the recommendations developed during the mission are taken into account. First Deputy Minister Hodjaev indicated that the Ministry of Health would study the recommendations in the final mission report carefully and requested further assistance in preparing the pilot activities.

The leads of the WHO/IARC expert team thanked First Deputy Minister Hodjaev for the continued interest in cooperation and affirmed the willingness to provide further technical and scientific support, provided adequate resources are available.

5 Discussion and conclusions

5.1 Methodological limitations

The methodology of this WHO/IARC expert mission has some limitations that restricted the scope and the depth of the observations and recommendations made during the mission and formulated in greater detail below. These limitations result primarily from resource restrictions in preparing and conducting the mission. The scope and the level of detail in the relevant data on the performance of the current national programme of prophylactic examinations that was collected prior to the mission were necessarily limited by these restrictions. For the same reason, it was not possible to engage a cytopathologist highly experienced in population-based cervical cancer screening to participate in the mission. Furthermore, the available time and financial resources did not permit auditing of the technical and professional performance of the reference facilities visited during the mission, nor was it possible to visit facilities beyond the Minsk area.

The authors of this report are, however, highly experienced in their respective areas of competence, and the mission team included experts highly experienced in implementation and quality assurance of population-based breast and cervical cancer screening programmes. Thus, the authors of the report have concluded that the information collected prior to and during the mission has been sufficient to justify the recommendations and conclusions in the report.

5.2 Current status of breast and cervical cancer prevention and control in Belarus

The strengths and weaknesses of the current situation were discussed with the Ministry of Health on 18 February 2011. The following discussion takes the previously mentioned points into account.

5.2.1 Strengths

The current situation reveals important advantages, which are lacking in a number of other countries currently seeking to improve control of breast and cervical cancer. These include:

- a highly developed health care infrastructure with a high density of medical and paramedical staff;
- a highly developed system of primary health care with high acceptance in the population;
- a well-established system of early detection of breast and cervical cancer that is anchored in the primary health care system and that includes sufficient capacity for cervical sampling;
- the potential to capitalize on the existing elements of the primary health care system, which could improve the acceptance and the efficiency of new population-based screening programmes;
- the existence of specialist facilities with the potential to develop into reference and training centres for population-based screening programmes;
- an appreciation of the importance of a programmatic approach to public health interventions aimed at lowering the burden of the disease in the population.

5.2.2 Weaknesses

- A major weakness is the lack of experience in the quality-assured process of implementation of population-based screening programmes, which generally takes 10 years or

more from the beginning of programme planning to the completion of feasibility testing, piloting and phased rollout across a country. Such experience is invaluable in managing the long time frame of the implementation process.

- A further weakness is the lack of detailed data on performance of the current services. The lack of information makes it more difficult to identify opportunities for improvement and for cost-effective reallocation of resources, which are likely to develop during the implementation process.

- There appears to be little involvement of civil society in the planning of new breast and cervical cancer screening programmes to date.[6]

5.2.3 Opportunities

- Control of breast and cervical cancer could be improved by implementation of population-based screening programmes that fulfil the quality criteria recommended by the EU.
- Implementation of population-based cancer screening programmes of high quality stimulates improvement in the quality and effectiveness of symptomatic care. This also provides benefits to women with a cancer that is diagnosed outside the screening programmes.
- Following the quality-assured process of screening programme implementation will provide the opportunity to test more effective screening modalities than those currently adopted in Belarus, such as primary HPV testing in women age 30 and above. It also provides the opportunity to begin screening in a restricted age range, with gradual expansion to the full age range when women are invited to the next screening round.
- Development of a model programme for implementation of population-based screening programmes in Belarus could be attractive to external funders, such as the EU, the Russian Federation or non-profit organizations.

5.2.4 Threats

To a certain degree, the strengths of the Belarus situation also involve risks.

- In general, it is more difficult to transform an existing opportunistic programme into a population-based programme because very large numbers of women and large numbers of health professionals are required to change well-established procedures and behaviour. There is an inherent danger that the potential resistance to change in the current system will prevent effective implementation of the new programmes.
- The current system of prophylactic examinations for breast and cervical cancer is embedded in a highly developed system of primary care. Attempts to substantially modify or remove the current elements dealing with breast and cervical cancer early detection, unless prepared and executed carefully, may have negative effects on the overall system of prophylactic examinations or even the overall system of primary care.
- Without strong involvement of civil society, particularly representatives of the target population, there is a danger that participation in screening will be low due to a lack of understanding and a lack of effective communication of the benefits and risks of screening.

[6] This impression may be incorrect. It results from a lack of involvement of representatives of civil society in the discussions during the mission.

5.3 National and international consensus

Consensus of national experts on key coordinates of the new breast and cervical cancer screening programmes currently being planned by the responsible authorities was achieved in the discussions during the mission and is documented above (see Tables 6–9). The WHO/IARC experts participating in the mission verified the conformity of these coordinates with current internationally recognized standards of best practice. At the request of the responsible authorities and the national experts who participated in the consensus workshop on 17 February 2011, additional recommendations have been made by the WHO/IARC experts that take into account the experience in the EU in successful implementation of population-based breast and cervical cancer screening programmes (see below and Table 1).

5.4 Programme management

In light of the current situation of breast and cervical cancer prevention and early detection in Belarus, in which opportunities but also complex risks exist, the most important recommendation that can be made at this time is to follow the quality-assured process of screening programme implementation that has been successful in the EU (Table 5). Planning followed by feasibility testing, piloting and phased rollout across the country will enable the responsible authorities to control the implementation process and to verify, before substantial resources are consumed, that requisite changes to current practice will effectively minimize risks and maximize benefits. This approach also saves time in the lengthy implementation process because common pitfalls encountered in other programmes can be avoided through international cooperation and collaboration.

Effective coordination of all activities, including quality assurance, is the hallmark of the quality-assured process of screening programme implementation. Coordination is essential because the complexity of the multidisciplinary approach to breast and cervical cancer screening, the long duration of the process and the potentially conflicting interests of the many organizations and individuals involved make it impossible to manage overall screening performance without effective coordination of all activities. Effective coordination requires an autonomous organization with managerial and budgetary control of programme activities.

5.5 Role of responsible authorities

The role of the responsible authorities should be to provide oversight, political support and adequate, sustainable resources for the programme, including particularly coordination and quality assurance. As recommended by WHO, these efforts should not be conducted in isolation, but integrated into an overall framework of comprehensive cancer control [16].

5.6 Action plan

A plan of action is proposed (Table 1) that takes into account the analysis of the current situation of breast and cervical cancer control in Belarus and the recommendations in this report. Consultation of competent independent experts is recommended throughout the process, particularly in developing and revising plans for feasibility testing, piloting and rollout, and in training, monitoring and evaluation. Given the exemplary nature of the recommended activities, consideration could be given to seeking co-funding for programme development from external sources.

Table 1: Action plan for establishing population-based breast and cervical cancer screening in Belarus

1. Governance
   - Establish steering committee
   - Appoint responsible coordinator of breast and cervical cancer screening pilot programmes
   - Establish expert advisory board (include representatives of civil society)
   - Develop proposal for financing phases 2 and 3

2. Coordinator prepares workplans (for discussion with advisory board and approval by steering committee)
   - Feasibility testing
   - Piloting
   - Budgets
   - Organizational development (pilot leads, reference centres and other capacity for direct scientific and technical support)

3. Feasibility testing in small-scale studies
   - Screening modalities (invitation, testing, diagnostic work-up, treatment)
   - Quality assurance
   - Revision of workplans, depending on results

4. Initial workshops and other training for screening and other relevant staff (continuous process adapted to scale of programme activities)

5. Pilot testing (large-scale, “routine” setting)
   - Region with minimum of 500 000 general population
   - Two rounds of breast screening (2-year interval)
   - Similar time period (at least 5 years) for cervical screening
   - Screening modalities (invitation, testing, diagnostic work-up, treatment)
   - Monitoring and managing performance
   - Other aspects of quality assurance, including training
   - Reporting results
   - Revision of workplans, depending on results

6. Management and evaluation unit for the national programme
   - Establish organizational entity for monitoring and evaluation
   - Develop database for nationwide programme implementation
   - Develop infrastructure for nationwide delivery of personal invitations
   - Monitor results of the programme, and develop performance indicators
   - Develop quality criteria for phased rollout, and revise workplans accordingly

7. Countrywide rollout of the breast and cervical cancer screening programmes after elaborating the same issues (see 5 and 6) in programme management.
   - Phased rollout, beginning in a given region only after quality criteria are fulfilled
   - Monitor results of the programme, and develop performance indicators

8. Continuous quality improvement of programme based on
   - Performance monitoring and impact evaluation
   - International collaboration in quality assurance.

6 References

1. Wilson JMG, Jungner G. Principles and practice of screening for disease. Geneva, World Health Organization, 1968 (WHO Public Health Papers, No. 34) (http://whqlibdoc.who.int/php/WHO_PHP_34.pdf, accessed 12 April 2011).
2. Council of the European Union (2003). Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC). *Off J Eur Union*, L 327:34–38.
3. Lansdorp-Vogelaar I, von Karsa L. Introduction. In: Segnan N, Patnick J, von Karsa L, eds. *European guidelines for quality assurance in colorectal cancer screening and diagnosis*, 1st ed. Luxembourg, European Commission, Publications Office of the European Union, 2010:1–32.
4. von Karsa L (1995). Mammographie Screening – umfassendes, populationsbezogenes Qualitätsmanagement ist hier gefragt! [Mammography screening – comprehensive, population-based quality assurance is required!] *Z Allgemeinmed*, 71:1863–1867.
5. Perry N, Broeders M, de Wolf C *et al.*, eds. *European guidelines for quality assurance in breast cancer screening and diagnosis*, 4th ed. Luxembourg, Office for Official Publications of the European Communities, 2006 (http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-breast-cancer-screening-and-diagnosis-pbND7306954/, accessed 27 December 2011).
6. Arbyn M, Anttila A, Jordan J *et al.*, eds. *European guidelines for quality assurance in cervical cancer screening*, 2nd ed. Luxembourg, Office for Official Publications of the European Communities, 2008 (http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-cervical-cancer-screening-pbND7007117/, accessed 27 December 2011).
7. Segnan N, Patnick J, von Karsa L, eds. *European guidelines for quality assurance in colorectal cancer screening and diagnosis*, 1st ed. Luxembourg, European Commission, Publications Office of the European Union, 2010 (http://bookshop.europa.eu/en/european-guidelines-for-quality-assurance-in-colorectal-cancer-screening-and-diagnosis-pbND3210390/, accessed 27 December 2011).
8. Arbyn M, Anttila A, Jordan J *et al*. (2010). European guidelines for quality assurance in cervical cancer screening. Second edition – summary document. *Ann Oncol*, 21:448–458.
9. Perry N, Broeders M, de Wolf C *et al.* (2008). European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition – summary document. *Ann Oncol*, 19:614–622.
10. Quirke P, Risio M, Lambert R *et al.* (2011). Quality assurance in pathology in colorectal cancer screening and diagnosis – European recommendations. *Virchows Arch*, 458:1–19.
11. von Karsa L, Anttila A, Ronco G *et al. Cancer screening in the European Union. Report on the implementation of the Council Recommendation on cancer screening*, first report. Luxembourg, European Commission, 2008.
12. Ferlay J, Shin HR, Bray F *et al.* GLOBOCAN 2008, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet], Lyon, International Agency for Research on Cancer, 2010.
13. *Report from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions – Implementation of*

the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC). Brussels, Commission of the European Communities, 2008, COM(2008) 882 final.

14. von Karsa L, Arrossi S. [Development and implementation of guidelines for quality assurance in breast cancer screening – the European experience]. *Salud Publica Mex*, In press.
15. Lynge E, Törnberg S, von Karsa L *et al.* (2012). Determinants of successful implementation of population-based cancer screening programmes. *Eur J Cancer*, 48:743–748.
16. *Cancer control: knowledge into action. WHO guide for effective programmes. Planning*. Geneva, World Health Organization, 2006 (http://www.who.int/cancer/modules/Planning%20Module.pdf, accessed 12 April 2011).

7 List of abbreviations

ASC-US
Atypical squamous cells of undetermined significance (according to the terminology of the Bethesda system, version 2001) [6]

CE
Conformité Européenne (European Conformity)

ER
Estrogen receptor

EU
European Union

HER2
Human epidermal growth factor receptor 2

HPV
Human papillomavirus

IARC
International Agency for Research on Cancer

LSIL
Low-grade squamous intraepithelial lesion

MRI
Magnetic resonance imaging

PCR
Polymerase chain reaction

PR
Progesterone receptor

WHO
World Health Organization

Current Status and Future Directions of Breast and Cervical Cancer Prevention and Early Detection in Belarus

Annexes

A1. Excerpt from: Perry N. et al. - European guidelines for quality assurance in breast cancer screening and diagnosis. ***Fourth Edition***, 2006

A2. European guidelines for quality assurance in breast cancer screening and diagnosis. ***Fourth Edition*** – link to 400-page Guidelines

A3. Excerpt from: Arbyn M. et al. - European guidelines for quality assurance in cervical cancer screening. ***Second Edition***, 2008

A4. European guidelines for quality assurance in cervical cancer screening. ***Second Edition*** – link to 300-page Guidelines

A5. Cervical cancer prevention and management in Belarus - template for preparation of the background situation analysis

A6. Letter from the Ministry of Health of Belarus

A7. Questions for preparation of planning of breast cancer screening in Belarus – template

A8. Questions for preparation of planning of breast cancer screening in Belarus – responses

A9. Breast cancer epidemiology tables for Belarus

A10. Mammography equipment in health care facilities of Belarus

A11. Equipment for radiological therapy in the health care facilities of Belarus

A12. Cervix cancer screening form - Russian

A13. Cervix cancer screening form - English

A14. Seminar programme

A15. Migal T.F. – Belarusian Health Care System - Russian

A16. Putyrski L.A. – The role of breast self-examination and clinical examination in early detection of breast cancer

A17. Litvinova T. M. – Cervical cancer in the Republic of Belarus

A18. Klukina L.B. & Erokhina O.A. – Cytological practice in medical examination of female population of the Republic of Belarus

A19. von Karsa L. – Implementation of cancer screening in the European Union

A20. Dean P.B. – Nationwide mammography screening: major issues associated with introduction of the program

A21. Suonio E. – About cervical cancer screening guidelines

Appendix 1

Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)

Excerpt from:

European Commission

European guidelines for quality assurance in breast cancer screening and diagnosis - Fourth Edition.

Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L, Puthaar E (eds.)

Luxembourg: Office for Official Publications of the European Communities, 2006

ISBN 92-79-01258-4

This document has been prepared with financial support from the European Commission (Grant agreement SPC.2002482).

To order or download the full guidelines document, go to:

European guidelines for quality assurance in breast cancer screening and diagnosis - Health policy - EU Bookshop

Breast cancer is currently the most frequent cancer and the most frequent cause of cancer-induced deaths in women in Europe. Demographic trends indicate a continuing increase in this substantial public health problem. Systematic early detection through screening, effective diagnostic pathways and optimal treatment have the ability to substantially lower current breast cancer mortality rates and reduce the burden of this disease in the population.

In order that these benefits may be obtained, high quality services are essential. These may be achieved through the underlying basic principles of training, specialisation, volume levels, multidisciplinary team working, the use of set targets and performance indicators and audit. Ethically these principles should be regarded as applying equally to symptomatic diagnostic services and screening.

The editors of the fourth edition have maintained focus on screening for breast cancer while at the same time supporting the provision of highly effective diagnostic services and the setting up of specialist breast units for treatment of women, irrespective of whether a breast lesion has been diagnosed within a screening programme or not. By so doing we support the resolution of the European Parliament in June 2003 (OJ C 68 E, 2004), calling on the EU member states to make the fight against breast cancer a health policy priority and to develop and implement effective strategies for improved preventive health care encompassing screening, diagnosis and treatment throughout Europe.

The primary aim of a breast screening programme is to reduce mortality from breast cancer through early detection. Unnecessary workup of lesions which show clearly benign features should be avoided in order to minimise anxiety and maintain a streamlined cost-effective service. Women attending a symptomatic breast service have different needs and anxieties and therefore mixing of screening and symptomatic women in clinics should be avoided.

Our incorporation of additional text and sections on diagnostic activity has resulted in an expanded fourth edition. We have prepared this Executive Summary in an attempt to underline what we feel to be the key principles that should support any quality screening or diagnostic service. However the choice of content is to some extent arbitrary and cannot in any way be regarded as an alternative to the requirement for reading each chapter as a whole, within the context of the complete guidelines.

Fundamental points and principles

- In June 2003 the European Parliament called for establishment of a programme by 2008 which should lead to a future 25% reduction in breast cancer mortality rates in the EU and also a reduction to 5% in the disparity in the survival rates between member states (OJ C 68 E, 2004).

- Implementation of population-based breast screening programmes, prioritisation of quality assurance activities such as training and audit, together with the setting up of specialist breast units for management of breast lesions detected inside or outside screening programmes are regarded as essential to achieving these aims.

- Results of randomised trials have lead to the implementation of regional and national population based screening programmes for breast cancer in at least 22 countries within the past 20 years (Shapiro et al. 1998).

- An international agency for research on cancer (IARC) expert working group, has reviewed the evidence and confirmed that service screening should be offered as a public health policy directed to women age 50-69 employing two-yearly mammography (IARC Working Group on the Evaluation of Cancer Preventive Strategies 2002). This is consistent with the European Council Recommendation Recommendation of 2 December 2003 on Cancer Screening (OJ L 327/34-38).

- Breast cancer screening is a complex multidisciplinary undertaking, the objective of which is to reduce mortality and morbidity from the disease without adversely affecting the health status of participants. It requires trained and experienced professionals using up-to-date and specialised equipment.

- Screening usually involves a healthy and asymptomatic population which requires adequate information presented in an appropriate and unbiased manner in order to allow a fully informed choice as to whether to attend. Information provided must be balanced, honest, adequate, truthful, evidence-based, accessible, respectful and tailored to individual needs where possible.

- Mammography remains the cornerstone of population-based breast cancer screening. Due attention must be paid to the requisite quality required for its performance and interpretation, in order to optimise benefits, lower mortality and provide an adequate balance of sensitivity and specificity.

- Physico-technical quality control must ascertain that the equipment used performs at a constant high quality level providing sufficient diagnostic information to be able to detect breast cancer using as low a radiation dose as is reasonably achievable. Routine performance of basic test procedures and dose measurements is essential for assuring high quality mammography and comparison between centres.

- Full-field digital mammography can achieve high image quality and is likely to become established due to multiple advantages such as image manipulation and transmission, data display and future technological developments. Extensive clinical, comparative and logistical evaluations are underway.

- The role of the radiographer is central to producing high quality mammograms which, in turn, are crucial for the early diagnosis of breast cancer. Correct positioning of the breast on the standard lateral oblique and cranio-caudal views is necessary to allow maximum visualisation of the breast tissue, reduce recalls for technical inadequacies and maximise the cancer detection rate.

- Radiologists take prime responsibility for mammographic image quality and diagnostic interpretation. They must understand the risks and benefits of breast cancer screening and the dangers of inadequately trained staff and sub-optimal equipment. For quality loop purposes the radiologist performing the screen reading should also be involved at assessment of screen detected abnormalities.

- All units carrying out screening, diagnosis or assessment must work to agreed protocols forming part of a local quality assurance (QA) manual, based on national or European documents containing accepted clinical standards and published values. They should work within a specialist framework, adhering to set performance indicators and targets. Variations of practices and healthcare environments throughout the member states must not interfere with the achievement of these.

- A robust and reliable system of accreditation is required for screening and symptomatic units, so that women, purchasers and planners of healthcare services can identify those breast clinics and units which are operating to a satisfactory standard. Any accreditation system should only recognise centres that employ sufficiently skilled and trained personnel.

- The provision of rapid diagnostic clinics where skilled multidisciplinary advice and investigation can be provided is advantageous for women with significant breast problems in order to avoid unnecessary delay in outline of management planning or to permit immediate discharge of women with normal/benign disease.

- Population breast screening programmes should ideally be based within or closely associated with a specialised breast unit and share the services of trained expert personnel.

- All staff in a screening programme should:
  - Hold professional qualifications as required in each member state
  - Undertake specialist training
  - Participate in continuing medical education and updates
  - Take part in any recognised external quality assessment schemes
  - Hold any necessary certificate of competence

- Each screening unit should have a nominated lead professional in charge of overall performance, with the authority to suspend elements of the service if necessary in order to maintain standards and outcomes.

- All units involved in screening, diagnostic or therapeutic activities must ensure the formation of proper multidisciplinary teamwork involving a full range of specially trained professionals including a radiologist, radiographer, pathologist, surgeon, nurse counsellor and medical oncologist/radiotherapist.

- All women requiring breast surgery or other treatment should have their clinical, imaging and pathology findings discussed and documented in regular pre-operative and post-operative meetings of the full multi-disciplinary team.

- The surgeon must ensure that women receive information on treatment options and be aware that breast conserving surgery is the treatment of choice for the majority of small screen-detected cancers. Where appropriate, patients should be offered a choice of treatment including immediate or delayed breast reconstruction should mastectomy be required.

- The pathologist is a key member of the multidisciplinary team and must participate fully in pre-operative and post-operative case discussions. Accurate pathological diagnosis and the provision of prognostically significant information are vital to ensure appropriate patient management as well as accurate programme monitoring and evaluation.

- Patient support must be provided by specialist breast care nurses or appropriately psychologically professionally trained persons with expertise in breast cancer. They must be available to counsel, offer practical advice and emotional support.

- Quality assurance programmes should be mandatory for breast cancer services in order to qualify for funding from healthcare providers.

- Evaluation of the impact of screening requires the complete and accurate recording of all individual data pertaining to the target population, the screening test, its result, decisions made and the eventual outcome in terms of diagnosis and treatment.

- The protection of individual data is a basic right of every citizen in the EU – however, if appropriate precautions are taken, personal data may be used for promotion of public health.

References

Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC) OJ L 327/34-38.

European Parliament Resolution. "Breast Cancer in the European Union", OJ C 68 E (18.03.2004) p. 611.

IARC Working Group on the Evaluation of Cancer Preventive Strategies. Breast cancer screening. IARC Handbooks of Cancer Prevention, volume 7. Lyon: IARC Press, 2002, ISBN 92 832 300 8.

Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) European Guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. Office for Official Publications of the European Communities, Luxembourg.

Shapiro S, Coleman EA, Broeders M, Codd M, de Koning H, Fracheboud J, et al. for the International Breast Screening Network, and the European Network of Pilot Projects for Breast Cancer Screening. Breast cancer screening programmes in 22 countries: current policies, administration and guidelines. Int J Epidemiol 1998;27:735-42.

Summary table of key performance indicators

Introduction

For ease of reference we have included a summary table of key performance indicators from these guidelines. Please note that the numbering of the indicators is not indicative of importance. For more complete information regarding definition and context, further reference should be made to the source of each parameter within the text as listed. On occasions we have had to accept that different disciplines and different Member States show some variation of priorities and target levels. In all cases we have attempted to list what we regard as the most widely used and generally appropriate professionally agreed levels for usage in a Pan-European setting. In any case, all targets should be constantly reviewed in the light of experience and revised accordingly with regard to results achieved and best clinical practice. As far as possible, targets given refer to women over 50 years of age attending a screening programme.

Abbreviations used for reference to the chapters, e.g.:
3T1 Chapter 3, table 1
4.7 Chapter 4, paragraph 7

Performance indicator	Acceptable level	Desirable level
1. Target optical density[2AT4.1]	1.4 - 1.9 OD	1.4 - 1.9 OD
2. Spatial resolution[2AT4.1]	> 12 lp/mm	> 15 lp/mm
3. Glandular dose – PMMA thickness at 4.5 cm[2AT4.1]	< 2.5 mGy	< 2.0 mGy
4. Threshold contrast visibility[2AT4.1]	< 1.5%	< 1.5%
5. Proportion of women invited that attend for screening[1T32]	> 70%	> 75%
6. Proportion of eligible women reinvited within the specified screening interval[1T32]	> 95%	100%
7. Proportion of eligible women reinvited within the specified screening interval + 6 months[1T32]	> 98%	100%
8. Proportion of women with a radiographically acceptable screening examination[3.8, 5.4.3.1]	97%	> 97%
9. Proportion of women informed of procedure and time scale of receiving results[3.8, 5.4.3.1]	100%	100%
10. Proportion of women undergoing a technical repeat screening examination[1T32, 3.8, 4T2, 5.4.3.1]	< 3%	< 1%
11. Proportion of women undergoing additional imaging at the time of the screening examination in order to further clarify the mammographic appearances[1T32]	< 5%	< 1%
12. Proportion of women recalled for further assessment[1T32, 4T2]		
• initial screening examinations	< 7%	< 5%
• subsequent screening examinations	< 5%	< 3%

Performance indicator	Acceptable level	Desirable level
13. Proportion of screened women subjected to early recall following diagnostic assessment[4T2]	< 1%	0%
14. Breast cancer detection rate, expressed as a multiple of the underlying, expected, breast cancer incidence rate in the absence of screening (IR)[1T33, 4T1]		
• initial screening examinations	3 x IR	> 3 x IR
• subsequent-regular screening examinations	1.5 x IR	> 1.5 x IR
15. Interval cancer rate as a proportion of the underlying, expected, breast cancer incidence rate in the absence of screening[1T33]		
• within the first year (0-11 months)	30%	< 30%
• within the second year (12-23 months)	50%	< 50%
16. Proportion of screen-detected cancers that are invasive[1T33, 4T1]	90%	80-90%
17. Proportion of screen-detected cancers that are stage II+[1T33]		
• initial screening examinations	NA	< 30%
• subsequent-regular screening examinations	25%	< 25%
18. Proportion of invasive screen-detected cancers that are node-negative[1T33]		
• initial screening examinations	NA	> 70%
• subsequent-regular screening examinations	75%	> 75%
19. Proportion of invasive screen-detected cancers that are ≤ 10 mm in size[1T33, 4T1]		
• initial screening examinations	NA	≥ 25%
• subsequent-regular screening examinations	≥ 25%	≥ 30%
20. Proportion of invasive screen-detected cancers that are < 15 mm in size[7A.2]	50%	> 50%
21. Proportion of invasive screen-detected cancers < 10 mm in size for which there was no frozen section[5.8.2, 9T1]	95%	> 95%
22. Absolute sensitivity of FNAC[5.5.3, 6A A1.3]	> 60%	> 70%
23. Complete sensitivity of FNAC[5.5.3, 6A A1.3]	> 80%	> 90%
24. Specificity of FNAC[5.5.3, 6A A1.3]	> 55%	> 65%
25. Absolute sensitivity of core biopsy [5.5.3, 6A A1.3]	> 70%	> 80%
26. Complete sensitivity of core biopsy[5.5.3, 6A A1.3]	> 80%	> 90%
27. Specificity of core biopsy[5.5.3, 6A A1.3]	> 75%	> 85%
28. Proportion of localised impalpable lesions successfully excised at the first operation[4T2, 5.8.2, 7A.3]	> 90%	> 95%

Performance indicator	Acceptable level	Desirable level
29. Proportion of image-guided FNAC procedures with insufficient result[4T2, 5.5.2]	< 25%	< 15%
30. Proportion of image-guided FNAC procedures from lesions subsequently proven to be malignant, with an insufficient result[4T2, 5.5.2]	< 10%	< 5%
31. Proportion of patients subsequently proven to have breast cancer with a pre-operative FNAC or core biopsy at the diagnosis of cancer[7B.2]	90%	> 90%
32. Proportion of patients subsequently proven to have clinically occult breast cancer with a pre-operative FNAC or core biopsy that is diagnostic for cancer[7B.2]	70%	> 70%
33. Proportion of image-guided core/vacuum procedures with an insufficient result[4T2]	< 20%	< 10%
34. Benign to malignant open surgical biopsy ratio in women at initial and subsequent examinations[1T32, 4T2, 5.8.2, 7A.3]	≤ 1 : 2	≤ 1 : 4
35. Proportion of wires placed within 1 cm of an impalpable lesion prior to excision[4T2, 5.8.2, 7A.3]	90%	> 90%
36. Proportion of benign diagnostic biopsies on impalpable lesions weighing less than 30 grams[5.8.2, 7A.3]	90%	> 90%
37. Proportion of patients where a repeat operation is needed after incomplete excision[7A.4]	10%	< 10%
38. Time (in working days) between:		
• screening mammography and result[4T2]	15 wd	10 wd
• symptomatic mammography and result[5.9]	5 wd	
• result of screening mammography and offered assessment[4T2]	5 wd	3 wd
• result of diagnostic mammography and offered assessment[5.9]	5 wd	
• assessment and issuing of results[5.9]	5 wd	
• decision to operate and date offered for surgery[5.9]	15 wd	10 wd
39. Time (in working days) between:		
• screening mammography and result [1)]		
≤ 15 wd	95%	> 95%
≤ 10 wd	90%	> 90%
• symptomatic mammography and result [1)]		
≤ 5 wd	90%	> 90%
• result of screening mammography and offered assessment [1)]		
≤ 5 wd	90%	> 90%
≤ 3 wd	70%	> 70%

Performance indicator	Acceptable level	Desirable level
• result of symptomatic mammography and offered assessment [1)] ≤ 5 wd	90%	> 90%
• assessment and issuing of results [1)] ≤ 5 wd	90%	> 90%
• decision to operate and date offered for surgery [1)] ≤ 15 wd	90%	> 90%
≤ 10 wd	70%	> 70%

[1)] To assist in monitoring and comparing performance between and within screening programmes, this summary table of indicators includes recommendations on the minimum proportion of women who should observe acceptable and recommended time periods.

Health & Consumer Protection
Directorate-General

European guidelines for quality assurance in breast cancer screening and diagnosis

Fourth Edition

Editors
N. Perry
M. Broeders
C. de Wolf
S. Törnberg
R. Holland
L. von Karsa

Technical editor
E. Puthaar

Click here to go to the full Guidelines

Excerpt from:

European Commission

European guidelines for quality assurance in cervical cancer screening - Second Edition.

Arbyn M, Anttila A, Jordan J, Ronco G, Schenck U, Segnan N, Wiener HG, Herbert A, Daniel J, von Karsa L (eds.)

Luxembourg: Office for Official Publications of the European Communities, 2008

ISBN 978-92-79-07698-5

This document has been prepared with financial support from the European Communities through the Europe Against Cancer Programme (European Cervical Cancer Screening Network) and the EU Public Health Programme (European Cancer Network, Grant Agreement No. 2004309).

To order or download the full guidelines document, go to:

[European guidelines for quality assurance in cervical cancer screening - Health policy - EU Bookshop]

Executive Summary

Authors:
Marc Arbyn, Brussels, Belgium
Ahti Anttila, Helsinki, Finland
Joe Jordan, Birmingham, United Kingdom
Guglielmo Ronco, Turin, Italy
Ulrich Schenck, Munich, Germany
Nereo Segnan, Turin, Italy
Helene G. Wiener, Vienna, Austria
Amanda Herbert, London, United Kingdom
Lawrence von Karsa, IARC

Cancer is common in older people but cancer of the uterine cervix primarily affects younger women, with the majority of cases appearing between the ages of 35 and 50, when many women are actively involved in their careers or caring for their families. In the European Union (EU) 34 000 new cases and over 16 000 deaths due to cervical cancer are reported annually (Arbyn *et al.,* 2007a & c).

The burden of cervical cancer is particularly high in the new member states. The highest annual world-standardised mortality rates are currently reported in Romania and Lithuania (13.7 and 10.0/100 000, respectively) and the lowest rates in Finland (1.1/100 000). Governmental authorities, parliamentary representatives and advocates should be aware that the substantially higher dimension of this public health problem in the east of the EU requires special attention.

Among all malignant tumours, cervical cancer is the one that can be most effectively controlled by screening. Detection of cytological abnormalities by microscopic examination of Pap smears, and subsequent treatment of women with high-grade cytological abnormalities avoids development of cancer (Miller, 1993).

Cytological screening at the population level every three to five years can reduce cervical cander incidence up to 80% (IARC, 2005). Such benefits can only be achieved if quality is optimal at every step in the screening process, from information and invitation of the eligible target population, to performance of the screening test and follow-up, and, if necessary, treatment of women with screen-detected abnormalities.

Quality assurance of the screening process requires a robust system of programme management and coordination, assuring that all aspects of the service are performing adequately. Attention must be paid not only to communication and technical aspects but also to qualification of personnel, performance monitoring and audit, as well as evaluation of the impact of screening on the burden of the disease.

Population-based screening policy and organisation conforming to evidence-based standards and procedures provide the overall programmatic framework essential to implementation of quality assurance and are therefore crucial to the success of any cervical cancer screening programme.

Establishment of screening registries and linkage of individual screening data with cancer registry data, taking into account appropriate data protection standards and methods, are essential tools of monitoring and evaluation.

The first edition of the European Guidelines for Quality Assurance in Cervical Cancer Screening (Coleman *et al.,* 1993) established the principles of organised, population-based screening and was pivotal in initiating pilot projects in Europe. A number of countries have in the meantime developed organised, population-based screening approaches, which are illustrated in the second edition. It is hoped that this new guideline edition will have a greater impact on those countries in which opportunistic, rather than organised, population-based screening has been the preferred model in the past. Toward this end, considerable attention has been given to the essential aspects of developing an organised, population-based programme policy that minimises the adverse effects and maximises the benefits of screening.

The current recommendations are also particularly relevant to planning new cervical cancer screening programmes in Europe. Different solutions fulfilling the recommended methodological standards need to be implemented in different countries and regions with diverse levels of resources and general healthcare infrastructure.

More than a decade has passed since publication of the first guideline edition. The current, expanded edition therefore also includes extensive updates on technical details and documentation,

as well as assessment of new technologies, e.g.: liquid-based cytology, automated interpretation of Pap smears and testing for human papillomaviruses. The scope of the current guideline has also been extended to include comprehensive instructions prepared by a multi-disciplinary team of experts for general practitioners, gynaecologists and cytopathologists. Much more extensive recommendations on follow-up, diagnosis and management of women with positive cervical cytology have been added. This necessitated the incorporation in the second edition of a separate chapter on techniques and quality assurance in histopathology and, for the first time, detailed guidance for clinicians in dealing with abnormal cytology, including management according to the severity of cytological abnormalities and management of histologically confirmed cervical epithelial neoplasia.

A major further addition has been the inclusion of uniform indicators for monitoring programme performance and for identifying and reacting to potential problems at an early time. The indicators deal with screening intensity, test performance, and diagnostic assessment and treatment, and address aspects of the screening process that influence the impact, as well as the human and financial costs of screening. Standard tables have been provided for documenting screening policies, and for tabulating the person-based data used to generate the uniform performance indicators. The availability of these standardised tools will substantially improve data comparability and the exchange of experience and results between screening programmes in Europe. Such exchange, in turn, is esential to effective pan-European collaboration in implementing and continuously improving the quality and effectiveness of cervical cancer screening programmes.

Cervical cytology still is the cornerstone of cervical cancer prevention programmes in Europe, although new perspectives for other screening technologies are developing rapidly. The principles of quality assurance, performance monitoring and evaluation, and many of the procedures and methodological standards laid down in the current guideline edition are of equal relevance to cervical cancer screening based on other conceivable methods. It is therefore expected that the publication of the updated and revised second edition will also promote rigorous standards in the evaluation and application of new screening technologies, thereby improving the effectiveness of cervical cancer prevention in Europe.

Over the short and medium term, screening for cervical cancer precursors and management of screen-detected lesions will remain the most effective tool for cervical cancer prevention in Europe. However, the field of cervical cancer prevention is rapidly developing due to better understanding of the natural history of the disease. Persistent infection with one of 13 to 16 oncogenic human papillomavirus (HPV) types is now known to be a key prerequisite for development of cervical cancer. The overwhelming evidence linking HPV infection to cervical cancer has prompted the development of test systems to detect its nucleic acids as well as prophylactic and therapeutic vaccines.

Primary prevention by prophylactic vaccination against the HPV types that are causally linked with most cervical cancers in Europe, is likely to become a feasible option for cervical cancer control, provided the current cost of inoculation regimens is substantially reduced.

While prophylactic vaccination, primarily in young girls, may provide important future health gains, cervical screening will need to be continued. Neglecting cervical cancer screening due to the current availability of a vaccine could paradoxically lead to an increase in cancer cases and deaths. Development of comprehensive European guidelines on prevention of cervical cancer that appropriately integrate screening and vaccination strategies is a key aim of the next phase of guideline development activities supported by the EU Public Health Programme.

The current updated and expanded second guideline edition has been prepared by a multidisciplinary team of experts appointed by the European Commission from the former European Cervical Cancer Screening Network (ECCSN) established under the Europe Against Cancer Programme. In addition to the cytopathologists, epidemiologists, general practitioners, gynaecologists, histopathol-

ogists, virologists, and specialists in social science serving as editors and authors; experts from outside the ECCSN were also invited to write, review, and contribute to the development of the second edition. Besides the input of the 48 experts from 17 member states directly involved in the production of the guidelines, numerous comments and suggestions were provided by experts attending meetings held in Denmark, Finland, Greece, Hungary and Luxembourg from 2003 to 2006 by the ECCSN and the European Cancer Network (ECN) in which the former cancer screening networks have been consolidated in the current EU Public Health Programme.

A draft revised guideline was made available for public consultation at http://www.cancer-network.de in December 2003. The results of this consultation were incorporated into a new draft which was reviewed by experts invited by the International Agency for Research on Cancer (IARC) to Lyon, France, in June 2005. Two or three reviewers were invited for each chapter, in order to comment on the contents and to ensure that all relevant references available had been considered. The further revised guideline content was subsequently discussed with screening experts from 23 member states and one applicant country of the European Union at the ECN network meeting in February 2006. Since then, IARC has provided technical and scientific support to the editorial board and the authors for the final preparation of the guideline document.

The final recommendations and standards of best practice in the revised and updated second guideline edition are based on the expert consensus in the editorial board subsequent to the above-mentioned consultations and discussions. They take into account the available evidence of screening and diagnostic procedures and programmes. For assessing evidence of effectiveness two criteria were used: study type and study outcomes. Study types were ranked from high to low level evidence as following: (1) randomised clinical trials, (2) observational studies: case-control studies, cohort studies and (3) correlational studies (time trends, geographical comparisons). Outcomes of studies were ordered as: (1) reduction of mortality from cervical cancer, (2) reduction of incidence of invasive cervical cancer, (3) reduction of incidence of CIN3 or cancer (CIN3+), (4) increased detection of high-grade histologically confirmed cervical intra-epithelial neoplasia (CIN3+ or CIN2+), (5) increased test positivity rate without or small loss in positive predictive value for CIN2+. Throughout this guideline, scientific evidence on which the recommendations are based is indicated by references in the text. Where no observed data were available, outcomes simulated by mathematical models and expert opinion were accepted as lowest level of evidence.

The authors conducted systematic literature searches and used available systematic reviews and published meta-analyses. Publication of the handbook for cervical cancer prevention by the IARC Working Group on the Evaluation of Cancer Preventive Strategies in 2005, which included several ECN experts, was also helpful. Several pioneering population-based randomised trials have been conducted or are currently being conducted in various member states in recent years: liquid-based cytology (Italy, The Netherlands), automated cytological screening (Finland); HPV-based versus cytology and combined (cytology+HPV) screening (Finland, Italy, Netherlands, Sweden, UK). The results available from these trials were taken into account during the preparation of the second guideline edition up to July 2007. In addition, several meta-analyses were performed to assess the level of evidence of new screening or management methods: liquid-based versus conventional cytology; HPV testing in triage of minor cytological lesions to identify women needing further follow-up, in follow-up after treatment of CIN to predict success or possible failure of treatment; and in primary screening. In the meta-analyses performed for the current guideline edition it was only possible to assess cross-sectional outcomes (outcome types 4-5); an insufficient number of trials had reached longitudinal outcomes prior to final closure of chapter revisions in mid 2007. One additional meta-analysis concerned obstetrical adverse effects of treatment of pre-cancer lesions.

Fundamental points and principles

Screening policy

- The Council of the European Union has recommended implementation of population-based cervical cancer screening programmes to the EU member states, with quality assurance at all levels and in accordance with European guidelines (Council of the European Union, 2003).

- Screening recommended by the European Council and the European Guidelines is set up as a population-based public health programme, with identification and personal invitation of each woman in the eligible target population. In addition to invitation, the other steps in the screening process and the professional and organisational management of the screening service, including quality assurance, monitoring and evaluation, are well defined by programme policy, rules and regulations at the regional and national level.

- Designing a cervical cancer screening programme includes defining the screening policy, i.e. choosing the screening test systems, determining the target age group and the screening interval between normal test results (3 or 5 years), and establishing follow-up and treatment strategies for screen-positive women, taking into account the variation in background risk in target populations and the natural history of the disease, which is characterised by a rather long detectable pre-clinical period and substantial regression rates of the pre-cancerous lesions.

- Cervical cytology is the currently recommended standard test for cervix screening, which should start in the age range 20–30. It is recommended to continue screening at 3-5-year intervals until the age of 60 (Advisory Committee on Cancer Prevention, 2000; Boyle *et al.,* 2003) or 65 (Coleman *et al.* 1993; IARC, 2005). The upper limit should not be lower than 60 years (Advisory Committee on Cancer Prevention, 2000). Stopping screening in older women is probably appropriate among women who have had three or more consecutive previous (recent) normal cytology results.

- Special attention should be paid to the problem of older women who have never attended screening, as they exhibit increased risk for cervical cancer.

- Opportunistic screening, which takes place in clinical settings and depends on the initiative of the individual woman or her doctor, should be discouraged. Such activities are often characterised by high coverage in selected parts of the population which are screened too frequently, coexisting with a low coverage in other population groups with less socioeconomic status, and heterogeneous quality, resulting in limited effectiveness and poor cost-effectiveness.

Screening organisation, monitoring and evaluation

- The programme design must permit evaluation. An experimental design that is suitable for evaluation of new screening policies in organised settings is recommended.

- The success of a screening programme requires adequate communication with women, health professionals and persons responsible for the health care system.

- Moreover, a well-organised screening programme must reach high population acceptance and coverage, and must ensure and demonstrate good quality at all levels.

- The communication strategy for cervical cancer screening must be underpinned by robust ethical principles and ensure that the information developed is evidence-based, 'women-centred' and

delivered effectively, taking into account the needs of disadvantaged groups and enabling women to make an informed choice about participation at each step in the screening process.

- Population-based information must be established for continuous monitoring of screening process indicators. An appropriate legal framework is required for registration of individual data and linkage between population databases, screening files, and cancer and mortality registers. Indicators of screening programme extension and quality need to be regularly published

- The information system is an essential tool for managing the screening programme; computing the indicators of attendance, compliance, quality and impact; and providing feedback to involve health professionals, stakeholders and health authorities.

New screening technologies

- An observation that a new screening method detects more precursor lesions than the standard Pap smear does not sufficiently demonstrate improved effectiveness. Due to frequent regression of precursor lesions, high specificity is also required to avoid anxiety, unnecessary treatment and side effects. Evidence of effectiveness should preferentially be based on reduction of cancer morbidity and mortality. Nevertheless, reduction in incidence of grade 3 cervical intraepithelial neoplasia (CIN3), is a surrogate indicator of effectiveness.

- Prior to routine implementation of a new screening strategy, the feasibility, cost-effectiveness and quality assurance should be verified and the necessary training and monitoring should be organised. A randomised screening policy, which permits quality-controlled piloting of a new test or procedure in the context of an organised screening programme, is a particularly powerful tool for timely evaluation under real-life conditions.

Cytological methods

- The occurrence of false-negative and unsatisfactory Pap smears has prompted the development of liquid-based cytology (LBC) and automated screening devices. The quality of the evaluation of the performance of these technologies often was poor and rarely based on histologically defined outcomes using randomised study designs. In general, the proportion of unsatisfactory samples is lower in LBC compared to conventional cytology, and the interpretation of LBC requires less time. The cost of an individual LBC test is considerably higher, but ancillary molecular testing, such as high-risk HPV testing in the case of ASC-US, can be performed on the same sample. The economic advantage of LBC due to the reduction of recalls for a new sample depends on the existing rates of inadequate Pap smears, which are highly variable throughout Europe.

- An Italian population-based randomised study, recently confirmed that the sensitivity of LBC and conventional cytology are similar.

- Computer-assisted screening using LBC is currently being evaluated, but insufficient evidence is available for guidelines.

HPV-detection

- Several applications for HPV DNA detection have been proposed: 1) primary screening for oncogenic HPV types alone or in combination with cytology; 2) triage of women with equivocal cytological results; 3) follow-up of women treated for CIN to predict success or failure of treatment.

- HPV infections are very common and usually clear spontaneously. Detection of HPV DNA thus carries a risk of unnecessary colposcopies, psychological distress and possibly of overdiagnosis. The need to perform cervical cancer screening in an organised programme, rather than in an opportunistic setting, therefore applies particularly to screening based on HPV testing.

- Evidence from randomised studies and meta-analyses shows that triage of women with equivocal cytological lesions by HPV testing with the Hybrid-Capture 2 assay is more sensitive and equally specific in finding high-grade CIN compared to repeat cytology. There is also evidence indicating that HPV DNA detection predicts treatment failure more quickly than cytological follow-up.

- The high sensitivity of current HPV DNA detection methods yields very high negative predictive values even for adenocarcinoma precursors that often escape cytological detection. Recent cohort studies indicate a prolonged duration (up to ten years) of the negative predictive value of HPV testing. Nevertheless, further longitudinal research is necessary, preferably in an organised setting guaranteeing optimal follow-up, using randomised designs and targeting relevant outcomes.

- Current randomised controlled trials may demonstrate lower cumulative incidence of CIN3 and invasive cervical cancer as joint or separate outcomes in HPV-negative compared to cytology-negative women. The results of these trials are needed before screening policies for general primary HPV screening can be recommended in Europe. Such policies would also have to ensure that possible increases in the detection and management of less severe lesions are kept to an appropriate minimum. Introduction of primary HPV screening will require appropriate triage and counseling of HPV-positive women.

- Primary HPV screening should not be recommended without specifying the age group to be targeted, the screening interval, and the essential elements of quality assurance required for programme implementation. HPV screening in an opportunistic setting is not recommended, because adherence to the appropriate intervals and requisite quality control cannot be adequately assured under such conditions.

- Piloting with validated HPV DNA testing can be recommended if performed in an organised screening programme with careful monitoring of the quality and systematic evaluation of the aimed outcomes, adverse effects and costs. Rollout towards national implementation can be considered only after the pilot project has demonstrated successful results with respect to effectiveness (relative sensitivity, positive predictive value of the screening test, triage and diagnostic assessment) and cost-effectiveness, and after key organizational problems have been adequately resolved.

Guidelines for cytology laboratories

- Professional and technical guidelines must be followed to assure the collection and preparation of an adequate cervical cell sample (Arbyn *et al.*, 2007b).

- The quality of a cervical cytology laboratory depends on adequate handling and staining of the samples, screening and interpretation of the slides and reporting of the results. An appropriate balance must be achieved between the best patient care possible, laboratory quality assurance and cost effectiveness (Wiener *et al.*, 2007).

- Uniform grading of cellular abnormalities is an essential condition for registration and comparisons over time and between different settings. Laboratories should apply only a nationally agreed terminology for cytology that is translatable into the Bethesda reporting System (Herbert *et al.*, 2007). The CIN terminology should be reserved for describing histology.

Guidelines for histopathology

- Histopathology provides the final diagnosis on the basis of which treatment is planned, and serves as the gold standard for quality control of cytology and colposcopy. It is also the source of the diagnostic data stored at the cancer registry and used for evaluation of screening pro-

grammes. It is therefore important that histopathology standards are monitored and based on CIN or other internationally agreed-upon terminology.

- Histopathologists should be aware of, and familiar with, the nature of cytological changes that may be relevant to their reports.

- The accuracy of the histopathological diagnosis of tissue specimens depends on adequate samples, obtained by colposcopically directed punch biopsies (with endo-cervical curettage if necessary) or excision of the transformation zone or conisation. An accurate histological diagnosis further depends on appropriate macroscopic description, technical processing, microscopic interpretation and quality management correlating cytological and histological diagnosis.

Guidelines for management of screen-positive women

- A woman with a high-grade cytological lesion, a repeated low-grade lesion or with an equivocal cytology result and a positive HPV test should be referred for colposcopy. The role of colposcopy is to identify the location of the abnormal cells, to target taking of biopsies and to decide whether any treatment is required. Colposcopy should only performed by adequately trained health professionals.

- Colposcopy is sometimes proposed as an alternative screening method, but its specificity (and probably also its sensitivity) in primary screening is too low for this purpose.

- Guidelines are provided for the management of atypical squamous cells of undetermined significance (ASC-US) and high-grade squamous intra-epithelial lesions (HSIL). Guidelines for low-grade squamous intraepithelial lesions (LSIL) are difficult to delineate because current evidence does not indicate that any method of management is optimal. Repeat cytology or colposcopy are acceptable options, but HPV testing as an initial management option is not sufficiently selective for all women with LSIL. However, HPV testing in older women with LSIL can be considered.

- Quality assurance and collection of data on patient management are important elements of the management and follow-up of women referred with an abnormal cervical smear.

References

Advisory Committee on Cancer Prevention (2000). Recommendations on cancer screening in the European Union. Eur J Cancer **36,** 1473-1478.

Arbyn M., Autier P., & Ferlay J. (2007a). Burden of cervical cancer in the 27 member states of the European Union: estimates for 2004. *Ann.Oncol.* **18,** 1425-7.

Arbyn M., Herbert A., Schenck U., Nieminen P., Jordan J., McGoogan E. *et al.* (2007b). European guidelines for quality assurance in cervical cancer screening: recommendations for collecting samples for conventional and liquid-based cytology. *Cytopathology* **18**: 133-9.

Arbyn M., Raifu A.O., Autier P. & Ferlay J. (2007c). Burden of cervical cancer in Europe: estimates for 2004. *Ann. Oncol.* **18**: 1708-15.

Boyle P., Autier P., Bartelink H., Baselga J., Boffetta P., Burn J. *et al.* (2003). European Code Against Cancer and scientific justification: third version (2003). *Ann.Oncol.* **14**, 973-1005.

Coleman D., Day N., Douglas G., Farmery E., Lynge E., Philip J., & Segnan N. (1993). European guidelines for quality assurance in cervical cancer screening. Europe against cancer programme. Eur J Cancer **29A Suppl 4,** S1-S38.

Council of the European Union (2003). Council Recommendation of 2 December on Cancer Screening. Off J Eur Union **878,** 34-38.

Herbert A., Bergeron C., Wiener H., Schenck U., Klinkhamer P., Bulten J., *et al.* (2007). European guidelines for quality assurance in cervical cancer screening: recommendations for cervical cytology terminology. *Cytopathology* **18**: 213-9.

International Agency for Research on Cancer (2005). Cervix Cancer Screening. IARC Handbooks of Cancer Prevention, Vol. 10. IARCPress, Lyon.

Miller A.B. (1993). Cervical cancer screening programmes: Managerial guidelines. World Health Organization, Geneva.

Wiener H.G., Klinkhamer P., Schenck U., Arbyn M., Bulten J., Bergeron C. *et al.* (2007). European guidelines for quality assurance in cervical cancer screening: recommendations for cytology laboratories. *Cytopathology* **18**: 67-78.

7

Key performance indicators

Authors:
Guglielmo Ronco
Lawrence von Karsa
Ahti Anttila

Authors:
Guglielmo Ronco, Turin, Italy
Lawrence von Karsa, IARC
Ahti Anttila, Helsinki, Finland

Reviewers:
Nereo Segnan, Turin, Italy
Peter Sasieni, London, United Kingdom
Maja Zakelj, Ljubljana, Slovenia

Acknowledgements
The numerous comments and suggestions made by collaborating experts, particularly those attending meetings of the European Cervical Cancer Screening Network and the European Cancer Network are gratefully acknowledged.

7.1 Executive summary

A list of key performance indicators is provided for monitoring the screening process and for identifying and reacting to potential problems at an early time. The indicators address aspects of the screening process which influence the impact, as well as the human and financial costs of screening. Three groups of indicators can be distinguished:

1. **Screening intensity**. The proportion of the target population actually screened within the recommended interval is the main determinant of the success of a screening programme. However, too frequent testing increases financial and human costs with only marginal gain in reduction of incidence and mortality. The duration of the recommended screening interval must therefore be taken into account in monitoring and evaluating screening intensity. Indicators include: programme extension, compliance with invitation, coverage, and smear consumption.

2. **Screening test performance.** Essential indicators include the referral rates for repeat cytology and for colposcopy, as well as the positive predictive value of referral for colposcopy, the specificity of the screening test, and the rate of detection of histologically confirmed CIN.

3. **Diagnostic assessment and treatment**. Indicators include compliance to referral for repeat cytology and for colposcopy; treatment of high-grade lesions is also an essential performance indicator. The proportion of women hysterectomised for CIN serves as an indicator of extreme over-treatment.

Most of the key performance indicators can be directly computed from the tables presented in the annex of Chapter 2. However, a number of indicators are based on the incidence of invasive cervical cancers in women with different screening history. These indicators provide a more direct evaluation of the impact of screening, but they need to be computed over longer periods of time and linkage of screening registry data with cancer registry data is required for some indicators; see also section 5 in Chapter 2.

7.2 Screening intensity

Usually the most important factor contributing to the success of screening is **coverage**, i.e., the proportion of women in the target population actually screened at least once during the standard interval recommended by the screening programme (3 or 5 years). Measuring coverage directly requires computerised registration of all cytology and the capacity to link the findings of each woman individually. There can be problems regarding completeness of registration, in particular for tests performed outside an organised programme; in such cases estimates obtained from ad hoc surveys can be helpful. Coverage should be computed for the entire target age-group as defined by the national or regional screening policy, and also stratified by 5-year age group. Moreover, coverage should also be computed for the group of women aged 25-64, for whom evidence of screening effectiveness is most clear in almost all EU member states.

In order to attain high screening coverage, it is necessary to reach the entire target population. This means that all women in the target population must be invited every three (or five) years, i.e. about one-third (or one-fifth) of the target population per year.

Compliance with invitation may be a less relevant parameter if opportunistic cervical screening is widespread. It should be kept in mind; however, that participation in organised screening programmes, as opposed to opportunistic screening, has resulted in the greatest decrease in the incidence of cervical cancer. Compliance provides a measure of the effectiveness of sending invitations, and, in addition, it provides a measure of the perceived quality of the programme.

A measure of test **consumption** is also essential. A large excess of smears per screened woman compared to the volume justified by the existing screening protocol has been observed in many countries. This is inefficient. As is the case for coverage, reliable measures of test consumption would require complete registration of smears. Underestimates can result from incompleteness of Registration, particularly for smears performed outside the organised screening programme. Estimates obtained from ad-hoc surveys can be helpful in such cases; health insurance agencies are an additional potential source of information.

The **incidence of invasive cervical cancer in unscreened and underscreened women, including women** never screened and women who were screened at intervals longer than that which is recommended by the local programme provides a direct measure of the burden of disease resulting from lack of coverage.

7.3 Screening test performance

The **rate of referral for repeat cytology** and the **referral rate for colposcopy** are measures not only of economic cost but also of the burden on women (anxiety, time consumption), which must be kept as low as possible. These rates depend on the sensitivity and the specificity of the screening test, and also on the prevalence of disease and on locally adopted protocols. The prevalence of disease is higher at the initial than at subsequent screening episodes. Therefore, these rates should be computed separately for women at initial, and subsequent screening episodes; and they also should be broken down by category of cytological abnormality that caused the referral.

The referral rate for repeat cytology due to unsatisfactory smears provides an approximation of the proportion of unsatisfactory smears resulting from poor quality smear taking.

The **positive predictive value (PPV) of referral for colposcopy** for detection of histologically confirmed high-grade CIN is calculated based on the actual number of women having colposcopies performed. This indicator readily shows the number of colposcopies which must be performed in order to find one lesion requiring treatment. (This number is the reciprocal of PPV).

Overall PPV for all women referred for colposcopy depends largely on the local protocol for colposcopy referral. This parameter should therefore be computed by cytological category and for different grades of CIN. PPV depends essentially on specificity (and to a minor extent on sensitivity) but is also strongly influenced by disease prevalence. Therefore it should also be computed separately for women attending initial and subsequent screening. Since PPV varies with the prevalence of disease, **test specificity** should also be computed; this will also permit comparison of performance of cytology interpretation between different screening programmes. Since specificity cannot

be calculated directly from screening programme data, the following formula can be used for approximation: number of women with negative screening test results / (number of screened women – number of women with confirmed CIN).

The **detection rate (DR) of CIN** (particularly of CIN2 and CIN3) depends on how many lesions are present in the screened population (i.e., on disease prevalence) and on how many of them are actually identified (cross sectional sensitivity). Since the prevalence of disease varies geographically and is a priori unknown, it is difficult to use the DR as an indicator of sensitivity. In addition, the DR also depends on the criteria of interpretation of histology, which are subject to variation. Nevertheless, DR should be monitored and compared between European screening programmes. This will provide a tool for recognising variation in quality and for developing the descriptive epidemiology of CIN in Europe which is needed for further study to improve control of cervical cancer.

Unfortunately, no easily interpretable indicator of screening sensitivity can be collected in a screening monitoring system. It is therefore essential to link screening registry and cancer registry data. Although it is difficult to obtain comparable data, in principle comparison of the **incidence of cancers** which are detected in women **after** having findings of **normal cytology** to the expected incidence in the absence of screening provides a direct estimate of test sensitivity for invasive lesions (see: Monitoring and evaluation, Chapter 2, Section 2.5). Information on cervical cancer incidence among unscreened women can be considered, if adjustments for selection bias in relation to screening attendance or non-attendance are made. Correspondingly, estimates of screening episode sensitivity may be obtained from inclusion of all screened women in the follow-up of cervical cancers. For programme sensitivity, it is essential to consider also women invited, but not screened. Previous smears of women with screen-detected cancer should also be reviewed (mixed with those of other women who did not develop cancer in order to avoid over-interpretation)

In addition to the above parameters, the distribution of the interval to reporting (time between smear taking and result communication) should be monitored. It seems implausible that reporting delays which are not extreme could influence screening effectiveness. Nevertheless, such delay influences women's perception of the quality of service, which affects participation and anxiety.

7.4 Diagnostic assessment and treatment

An important condition for the success of a screening programme is that diagnostic assessment is actually performed when needed. Measuring **compliance with referral for colposcopy** requires systematic and complete registration of colposcopies. When a record is lacking in the colposcopy register, the patient or her doctor should be contacted to obtain information on whether the colposcopy was performed and to remind about the need for examination. Compliance with colposcopy should be computed for each category of cytology that was the reason for referral (more severe cytology being of greatest relevance). Clearly, compliance will be higher for longer time spans after referral. Therefore, compliance should be monitored for different time intervals.

Another condition crucial to screening effectiveness is actual delivery of requisite treatment, particularly for histologically confirmed CIN2 and CIN3.

Avoiding over-treatment is the other important target. The proportion of women with pre-invasive lesions who undergo hysterectomy is a major indicator of unnecessary treatment, although some hysterectomies result from co-existing pathology. Peer-review should be conducted to verify the ap-

propriateness of treatment in such cases. It must be kept in mind that relevant differences in the proportion of women with CIN who undergo hysterectomy suggest that local practice is the main cause of such differences. Due to frequent spontaneous regression, only a small proportion of low-grade lesions should be treated.

Absence of SIL (or of high-risk HPV infection) can be routinely monitored at 6-month follow-up of treated women. This parameter has therefore been included as an indicator of short–term quality of treatment.

The **incidence of cervical cancer** in women which was not detected by screening, although the screening cytology results were abnormal (i.e., **after abnormal cytology**), serves as a direct summary indicator of failure associated with diagnostic assessment and treatment. Different reasons for failure can be distinguished. For example, cervical cancer arising in women who did not comply with referral for colposcopy represents a failure in communication. Cases arising in women who had colposcopy, but without detection of CIN, represent failure in diagnostic accuracy, etc. To calculate this parameter, the screening history of each case of cervical cancer should be reviewed (see also Chapter 2, section 5.3), and those cases should be excluded in which cancer was detected as a result of screening.

The present parameters assume that cytology is used as the primary screening test, which is currently recommended. However, most of the present parameters may also be applied, with only small changes, if a different screening method (e.g. HPV DNA testing) is used. Depending on the respective screening test and the screening policy, the values of some parameters (e.g., DR, PPV or specificity) may be expected to change.

7.5 Definition of performance parameters in cervical cancer screening

For general instructions on calculation of the following parameters, see sections 7.1 to 7.4. Specific instructions are indicated below and in the annex to Chapter 2, which is cross referenced in a number of the following descriptions of the performance parameters.

For short-term monitoring purposes, the calculations in the annex to Chapter 2 are based on annually aggregated data. Additional aggregation over different periods of time is recommended, particularly over the full screening interval of a given screening programme (3 or 5 years) and is required for some of the performance parameters. Wherever possible, longer and shorter evaluation periods should also be considered.

For calculations for a given period of time, such as the recommended screening interval (3 or 5 years), the dates on which the period starts and ends, and the procedure for determining the target population should be recorded. For calculations based on the size of the target population, use the average over the given time period.

Note that parameters 6 (Incidence of invasive cancer in unscreened women), 14 (Cancer incidence after normal cytology) and 19 (Incidence of invasive cancer after abnormal cytology) require **linkage with cancer registry data**. The follow-up periods recommended for calculation of cervical cancer incidence are six months longer than the recommended screening interval of the respective programme (3.5 or 5.5 years). The purpose of adding one-half year to the screening inter-

val is to include screen-detected cancer at the next screening episode. Calculations based on longer follow-up periods are also recommended.

7.5.1 Screening intensity

1. Programme extension

- Programme extension should be calculated regionally and nationally.
- If an entire region or country is actively served by a screening programme or programmes, then the programme extension in that region or country is 100%.

$$\frac{\text{N women in target population of catchment area actively served by programme}}{\text{N women in target population of entire respective region or country}}$$

2. Coverage of the target population by invitation

- Length of period corresponds to interval between two negative smear tests recommended by screening programme policy.
- Stratification by 5-year age groups is recommended.

$$\frac{\text{N women invited in defined period (3 or 5 years)}}{\text{N resident women in target population}}$$

- Obtain data from Table B1 in annex to Chapter 2. Also calculate separately using eligible women as denominator.
- For short-term monitoring, also calculate separately for women invited in the most recent calendar year in which screening was performed.
- For interpretation, take into account whether all women are invited or only a subset (**see Table A2** in annex to Chapter 2).

3. Coverage of the target population by smear tests

- Calculate separately for subgroups of women defined by:

  1) invitational status:
     a. personally invited
     b. not personally invited
     c. unknown

  2) programme status, i.e., smear performed:
     a. within organised programme
     b. outside organised programme
     c. unknown

$$\frac{\text{N women screened at least once in defined interval (3 or 5 years)}}{\text{N resident women in target population}}$$

- Stratification by 5-year age groups is also recommended.
- Obtain data from **Table B2** in annex of Chapter 2 (denominator and numerator).
- Also calculate separately with eligible women as denominator

4. Compliance to invitation

- Consider women invited in a given period and those among them screened.
- A cut-off date of six months after the end of the respective period is recommended for determining whether a woman was screened in response to the invitation. If a different cut-off procedure is used, this should be specified.
- Obtain data from **Table B2** in annex of Chapter 2 (denominator and numerator).

$$\frac{\text{N invited women in a given period who were screened}}{\text{N invited women in that period}}$$

5. Smear consumption

- Include only screening smears (no repeat tests, e.g., after unsatisfactory smears or for follow-up) and count one test per 'screening episode'; see glossary.
- For denominator of a) see **Table B2**, annex to Chapter 2.

a) $$\frac{\text{N screening tests in 3 (5) years in the target population}}{\text{N women in the target population screened in the same period}}$$

b) Distribution of screened women by number of screening smears in the same period.

6. Incidence of invasive cancer in unscreened and underscreened women in a given interval (3.5 or 5.5 years)

- Include only fully invasive cancer cases and person-years of the women not attending screening at the regular interval, i.e. women not screened in the previous 3.5 (5.5) years.
- Link screening registry and cancer registry data and calculate incidence age-adjusted, and by age group, based on the entire female population in the age groups eligible to attend screening.
- Analyse by cancer morphology (squamous vs. non-squamous)
- Calculate separately (with appropriate denominators):
  a. women never screened
  b. women previously screened, but interval to last screening test >3.5 (5.5) years
  c. women never invited
  d. invited vs. not invited in respective round

$$\frac{\text{N fully invasive cancers detected in women not screened in a given interval (3.5 or 5.5 years)}}{\text{N person-years of women not screened in the same interval (3.5 or 5.5 years)}}$$

7.5.2 Screening test performance

7. Distribution of screened women by the results of cytology

- Obtain data from **Table B3** (numerator) and **Table B2** (denominator) in annex to Chapter 2.
- Use classification in table B2 in annex to Chapter 2.
- Calculate overall and separately for subgroups of women:
  a. for the regular screening interval and shorter time periods
  b. attending initial or subsequent screening

$$\frac{\text{N screened women with cytological diagnosis}}{\text{N screened women}}$$

8. Referral rate for repeat cytology

- Obtain data from **Table B4** (numerator) and **Table B2** (denominator) in annex to Chapter 2.
- Calculate separately:
  a. by cytology that resulted in recommendation to repeat
  b. for initial and subsequent screening

$$\frac{\text{N screened women advised to repeat test at shorter than regular interval}}{\text{N screened women}}$$

9. Compliance with referral for repeat cytology

- See **footnote** in **Table B4** (numerator) and **Table B4** (denominator) in annex to Chapter 2.
- Calculate separately:
  a. by cytology that resulted in recommendation to repeat
  b. for initial and subsequent screening

$$\frac{\text{N women screened following recommendation for repeat cytology}}{\text{N women recommended for repeat cytology}}$$

10. Referral rate for colposcopy

- Obtain data from **Table B5** (numerator) and from **Table B2** (denominator) in annex to Chapter 2.
- Calculate separately by:
  a. cytology that resulted in referral to colposcopy
  b. for initial and subsequent screening

$$\frac{\text{N screened women referred for colposcopy}}{\text{N screened women}}$$

11. Positive predictive value of referral for colposcopy

- Obtain data from **Table B7** in annex to Chapter 2.
- If the number of women, for whom colposcopy was performed is not known, estimate using number of women referred for colposcopy.
- Calculate overall and separately by:
  a. cytology (ASC-US+, LSIL+, HSIL+)
  b. histology (CIN1+, CIN2+, CIN3+, Invasive Ca)
  c. initial and subsequent screening

$$\frac{\text{N screened women who had colposcopy with histologically confirmed CIN+}}{\text{N screened women who had colposcopy}}$$

12. Test specificity

- Calculate overall, and separately by:
  a. cytology (<ASC-US, <LSIL, <HSIL)
  b. histology (CIN1+, CIN2+, CIN3+, Invasive Ca)
  c. initial and subsequent screening
- Test specificity cannot be computed from routine screening and follow-up data, because the true denominator is unknown. Nevertheless, the formulas on the right should be used to approximate specificity.
- Normal test results refer to 'negative for intraepithelial lesions' (i.e., results not leading to referral for follow-up or confirmation)

$$\frac{\text{N screened women not referred for colposcopy}}{\text{N screened women who had no histologically confirmed CIN+}}$$

$$\frac{\text{N screened women with normal screening test results}}{\text{N screened women who had no histologically confirmed CIN+}}$$

13. Detection rate by histological diagnosis

- Obtain data from **Table B7** (numerator) and **Table B2** (denominator) in annex to Chapter 2.
- Calculate separately:
  a. by histology (CIN1+, CIN2+, CIN3+, Invasive Ca)
  b. for the regular screening interval and shorter time periods
  c. for initial and subsequent screening

$$\frac{\text{N screened women with histologically confirmed CIN+}}{\text{N screened women}}$$

14. Cancer incidence after normal cytology

- Normal cytology refers to cases recommended for rescreening at the regular interval.
- Count only fully invasive cancers among the women who had a normal screening cytology in the previous 3.5 (5.5) years.
- Analyse by:
  a. interval from index cytology
  b. cancer morphology (squamous vs. non-squamous)
- Cytology should be reviewed mixed with that of other women not developing cancer.

$$\frac{\text{N screened women with fully invasive cervical cancer detected within 3.5 (5.5) years of normal cytology}}{\text{N person-years of screened women for same period after normal cytology}}$$

7.5.3 Diagnostic assessment and treatment

15. Compliance to referall for colposcopy

- Obtain data from **Table B6** (denominator) and **Table B8** (numerator) in annex to Chapter 2.
- Calculate separately by:
  a. different intervals after referral (3 months / 6 months)
  b. cytology that resulted in referral

$$\frac{\text{N screened women actually undergoing colposcopy}}{\text{N screened women referred for colposcopy}}$$

16. Treatment of high-grade intraepithelial lesions

- Obtain data from Table B9 in annex to Chapter 2.

$$\frac{\text{N women with screen-detected CIN2 or CIN3 treated}}{\text{N women with screen-detected CIN2 or CIN3}}$$

17. Proportion (%) of women hysterectomised on screen-detected intraepithelial lesions

- Obtain data from Table B9 in annex to Chapter 2.
- Calculate separately by histology (CIN1, CIN2, CIN3).
- Appropriateness of individual cases should be evaluated by peer review.

$$\frac{\text{N screened women with histological CIN hysterectomised}}{\text{N screened women with histological CIN}}$$

18. Proportion (%) of women treated on CIN1

- Obtain data from **Table B9** in annex to Chapter 2.
- Appropriateness of individual cases should be evaluated by peer review.

$$\frac{\text{N women with screen-detected CIN1 treated}}{\text{N women with screen-detected CIN1}}$$

19. Incidence of invasive cancer after abnormal cytology

- Include screened women:
  a. without colposcopy carried out, despite existing indication
  b. with colposcopy carried out, but no CIN detected
  c. with CIN detected, but not treated
  d. treated
  e. in diagnostic or post-treatment follow-up
- Calculate overall and separately for each of above subgroups.
- Include only fully invasive cancers.
- Exclude cases detected as a result of screening.

$$\frac{\text{N cases of invasive cancer in screened women after abnormal cytology}}{\text{N person-years of screened women after normal cytology}}$$

20. Proportion of women with cytology negative for SIL, 6 months after treatment

- Obtain data from **Table B10** in annex to Chapter 2.
- Include women treated for CIN2, CIN3, CGIN or AdenoCa in situ followed at least 6 months after treatment (denominator)
- Include women negative for hr-HPV (numerator), if this test is used for follow-up

$$\frac{\text{N screened and treated women with negative cytology after 6 months}}{\text{N screened and treated women followed-up for 6 months}}$$

European guidelines for quality assurance in cervical cancer screening

Second Edition

Editors
M. Arbyn
A. Anttila
J. Jordan
G. Ronco
U. Schenck
N. Segnan
H. G. Wiener
A. Herbert
J. Daniel (technical editor)
L. von Karsa

Click here to go to the full Guidelines

Cervical cancer prevention and management in BELARUS

Template for preparation of the background situation analysis

- Basic demographical and economic indicators and their trends (please, include the dynamics during last 10 years)

Population
Age distribution – female
male
Life expectancy at birth
Median age
Rural vs urban
Economic activity
GDP per capita
Total expenditure per health per capita
Population living below poverty line
Unemployment

- Sexual behaviour indicators

- age of sexual debut, disaggregated by age and sex
- % of women with more than 10 sexual partners per life time
- incidence of sexually transmitted infections, disaggregated by age and sex

- Reproductive health indicators

- contraceptive prevalence
- hormonal contraceptive prevalence
- condom use
- fertility rate

- HPV incidence (if available from research studies)

- Smoking % among women

Health services:

- External resources for health as percentage of total expenditure on health
- General government expenditure on health as percentage of total expenditure on health
- General government expenditure on health as percentage of total government expenditure
- Out-of-pocket expenditure as percentage of private expenditure on health
- Per capita government expenditure on health at average exchange rate (US$)
- Per capita total expenditure on health at average exchange rate (US$)
- Private expenditure on health as percentage of total expenditure on health
- Total expenditure on health as percentage of gross domestic product

- Burden of non-communicable diseases and cancer, trends
- Incidence (by stage and age groups if possible) and mortality of cervical cancer, trends

Cervical cancer screening

- Stakeholders involved in primary (vaccination) and secondary (screening) cervical cancer prevention and management

- National policies and programmes in the area of cervical cancer prevention and management

- National cancer registry

- Human resources involved in cervical cancer prevention and management – please, specify their training, roles and responsibilities and referral mechanisms

- Existing guidelines, protocols and algorithms in cervical cancer screening

- Activities aimed to raise awareness in community:
- Education and health promotion,
- Brochures, leaflets, web pages,
- Campaigns, etc
- Responsible institution(s) and organizations.

- Management of precancerous lesions – health professionals involved, available guidelines, monitoring schemes, etc.

- Available commodities and equipment including laboratories and colposcopy

Research (including operations research) on cervical cancer secondary prevention

- Research studies carried out during last 10 years – institutions, outcomes, (please, attach publications if available)

Ministry of Health of Belarus
Ul. Myasnikova 39, 220048 Minsk
Tel. 222 65 47, fax 222 46 27
Email: mzrb@belcmt.by
minzdrav@mailgov.by

02.12.2010 # 02-2-04/3907

Regional Office for Europe
World Health Organization
8, Scherfigsvej, DK-2100 Copenhagen,
Denmark
Dr. Jose M Martin-Moreno

WHO Country Office in Belarus
220007, Minsk, ul. Fabriciusa 28-401
E. Zaitsev

On provision of materials

For the benefit of the analysis of the existing cancer control policy and programmes and development of the technically sound project based on the results of the mission, the Ministry of Health of Belarus provides background materials on primary and secondary prevention of cervical carcinoma and breast cancer in Belarus.

Ms Tatiana Migal, Deputy Head, Department of Health Care, Ministry of Health of Belarus (tel. 8-017222-70-87), is responsible for the coordination of all relevant activities.

Minister V.I. Zharko

Cervical carcinoma prevention and treatment in Belarus

General demographic and economic indicators and trends (for 10 years)

Population

Population	2001	2005	As of 01.01.2010
Men	4 666 476	4 583 082	4 511 623
Women	5 284 464	5 216 991	5 160 289
Total	9 950 940	9 800 073	9 671 912

Life expectance at birth (2009) – 70.5 years: men – 64.7 years, women – 76.4 years.

Rural to urban population ratio as of 01.01.2010:
Rural population makes up for 26% of the total population. Ratio is 1:4.

Sexual behavior indicators
Start of the sexual life (age and gender):
Women – 14.5 years.
Men – 16 years.

Reproductive health indicators:
Use of contraception – 58%.
Use of hormonal contraception – 12%.
Use of condoms – 40%.
Birth rate (2009) – 11.5 per 1000 population.

Health care
External resources for health care, % of total health costs – 0.2%
Total government health costs, % of total health costs – 72%.
Total government health costs, % of total government costs – 8.3%.
Personal out of pocket payments, % of all personal health costs – 3%.
Government health costs per capita – 222 USD.
Total health costs per capita – 308 USD.
Personal health costs, % of total health costs – 18.9%.
Total health costs, % of GDP – 6.1%.

Cervical carcinoma incidence and mortality (by the stage of disease) and trends

Table 1 – Cervical carcinoma incidence per 100 000 female population/WORLD standard

Localization	2000	2004	2009
Cervical carcinoma	15.7/11.4	16.8/11.9	17.9/12.6

Table 2 – Cervical carcinoma cases by stages, %

	2004				2009			
	I-II	III	IV	not est.	I-II	III	IV	not est.
Cervical carcinoma	68.8	23.5	6.1	1.6	77.0	15.7	6.4	0.9

Table 3 – Cervical carcinoma mortality per 100 000 female population/WORLD standard

	2000	2004	2009
Cervical carcinoma	9.1/5.4	7.5/4.7	6.5/4.1

Cervical carcinoma screening

Stakeholders participating in cervical carcinoma control on primary (vaccination) and secondary (screening) levels:

Primary prevention of cervical carcinoma (vaccination) is organized in state health facilities and in private clinics. Cervarix and Gardasil are vaccines that are registered and approved in Belarus. Vaccination is voluntary and is paid for by the patients.

Secondary prevention of cervical carcinoma is organized by the general health care system (village first aid and obstetric stations, outpatients' clinics, examination rooms in policlinics, maternity clinics, rooms for prevention of tumors of female reproductive system) and in private clinics, where examinations are conducted and cervical smears are taken for cytological testing.

National cervical carcinoma prevention and treatment policies and strategies:

1966 – mobile cancer diagnostics and prevention station and women's examination rooms is created (by Professor N.N.Alexandrov, corresponding member of the Academy of Sciences of USSR).
1977 – 1978 – centralized cytological laboratories are established (Decree of MoH of BSSR #121 of 14.06.1977 "On organizing cytological laboratories").
1986 – Decree of MoH of USSR # 590 of 25.04.1986 "On further improvement of prevention, early detection and treatment of malignant tumors".
1987 – Decree of MoH of BSSR # 44 of 04.03.1987 "On further improvement of prevention, early detection and treatment of malignant growths".
1993 – cervical pathology rooms are established (Decree of MoH of Belarus # 24 of 08.02.1993 "On personnel arrangements for maternity clinics").
1998 – cervical pathology rooms are transformed into rooms for prevention and early diagnostics of tumors of female reproductive system (Decree of MoH of Belarus # 212 of 22.06.1998 "On improvement of female reproductive health").
2004 – Decree of MoH of Belarus # 205 "On improving the oncology services in Belarus". Medical and administrative standards for the rooms for prevention of tumors of female reproductive system are developed.

National oncology register:

In Belarus, registration of cancer on paper was introduced in 1953. In 1978, a computerized system was created. The current version of the automated information system on oncology was introduced in 1997. ICD-10 is used for the codification of the diagnosis. The morphological section of the International cancer classification, 2nd edition, is used for the codification of morphological forms of malignant new growths. Since 2004, D00-D09 codes of ICD-10 are used for the codification of cancers *in situ*.

Prevention and care personnel for cervical carcinoma, training, functions and system of referral:

Specialist obstetricians-gynecologists are responsible for the primary and secondary prevention, which is organized, for the most part, in outpatients' clinics and policlinics.

Oncological care is provided by specialist oncologists in oncology dispensaries. In Belarus, 55 physicians are practicing in oncological gynecology, of them 18 have the highest qualification category, 23 – 1st qualification category, and 11 – 2nd category. Four physicians have the Doctoral degree in Medicine, and 11 have Candidate's degree in Medicine.

Primary patient identification is based on preventive examinations and visits of patients with relevant symptoms in outpatients' clinics and polyclinics. For instance, if an specialist obstetrician-gynecologist suspects a cervical pathology during examination or according to the

cytology results, the patient is referred to the room for prevention of tumors of reproductive system for vaginoscopy and target biopsy, and also, if necessary, to the echoscopy of small pelvis. If a pathology is detected, the patient is referred for detailed examination (hysteroscopy and diagnostic curettage of cervical mucous membranes and endocervical cutterage) to a gynecological hospital. If severe cervical dysplasia or cervical carcinoma are identified, the patient is referred to the local oncological dispensary for further examination and care. After the specialized care, the follow-up is organized by the obstetrician-gynecologist and oncologist on the local level.

Current guidelines, protocols and methods for cervical carcinoma screening:
In Belarus, the system of annual prevention examinations for women in Belarus has existed for over 30 years. These examinations are the responsibility of specialist obstetricians-gynecologists and paramedical personnel on all tiers of health care – in village first aid stations, outpatients' clinics, examination rooms at policlinics and maternity clinics.

There is a uniform standard for examinations, that includes visual examination of externalia, taking a cervical smear for cytological testing, bimanual examination, examination and palpation of breasts and periphery lymph nodes. Each year, around 60% of women of all ages with sexual experience are examined. Examinations are funded from the budget.

Awareness raising, health education and health promotion:
Information about cancer and health promotion is being constantly provided through mass media, including TV, and meetings with female employees. Every year, Health days and Open door days are held, and leaflets on risks, prevention and treatment of cancer are issued.

Health workers are involved in the management of precancerous conditions, there are relevant guidelines and principles, monitoring schemes, etc.

Diagnostics and treatment of precancerous cervical conditions is usually organized in outpatients' facilities and is provided by specialist obstetricians-gynecologists of the general health care system.

Available tools and equipment, including laboratory equipment and vaginoscopy equipment:
Cervical smears are taken by disposable cytobrushes, that are produced in Belarus by "Simurg" in sufficient numbers and at an affordable price. In 2009, a guide "Tools and guidelines for taking samples for cytological testing for the preventive examinations of women" was adopted, that prescribes the necessary procedures for taking smears.

Each state health facility has sufficient capacity for examining women.

Examination for HPV infections is paid for the patients themselves. Pregnant women and patients that are referred to the examination by the protocols are examined at the costs of the budget.

Cytological smear testing is organized on the central level by the geographical principle. In Belarus, cytological tests are conducted in 41 facilities, of which 31 have centralized cytological laboratories doing cytological tests for diagnostic and preventive purposes, over 150 000 tests annually. Personnel arrangements for 2009 provide for 130 positions of specialist cytologists (cytopathologists) and 170 paramedical cytology lab workers (cytohistologists). Currently, 100 physicians and 144 paramedical lab workers are employed. Smear staining is based on the Pappenheim method. Tests are done on the two-tier basis: primary microscopy by the paramedical lab worker (cytotechnologist), while atypical cases are referred to the specialist

cytologist. Staffing level is 90%, but the personnel arrangements do not reflect the workload, and should be thus increased by 2 or 3 times. State health system includes 26 laboratories for molecular and genetic testing methods.

In Belarus, there are 129 rooms for prevention and early detection of tumors of female reproductive system that are equipped with vaginoscopes and other necessary tools and equipment (scalpels, conchotomes, electrocoagulators and laser surgical equipment). Equipment and qualification of the staff varies by the level of the facility.

The rooms are operating according to the Decree of the Ministry of Health of Belarus # 205 "On improving the oncology services in Belarus", and can conduct selective cervical carcinoma screening according to risk factors. Belarussian nationals receive these health services free of charge; women may also visit private clinics.

In Belarus, vaginoscopes with software are produced by "Ecomp" at prices affordable at all health facilities in the country.

Research activities in the last 10 years – facilities and results

The Department of oncogynecological pathologies of the N.N. Alexandrov National research hospital of oncology and medical radiology has undertaken the following studies during the last 10 years:

1. N.N. Alexandrov National research hospital of oncology and medical radiology, 2009. "Method of fluorescent diagnostic and photodynamic photolone therapy for the cases of cervical intraepitelic neoplasis II and III". Candidate's paper defended. Guidelines for use approved.
2. Vitebsk State Medical University, 2009. "HPV infection and cervical pathologies: clinical pathogenetical patterns, prognosis, treatment and prevention". Doctoral paper defended. Two guidelines for use approved.
3. Gomel State Medical University, 2006. "Dysplasia and early cervical carcinoma in women of young and middle age". Doctoral paper defended. Guidelines for use approved.
4. N.N. Alexandrov National research hospital of oncology and medical radiology, 2008-2010. A paper on "Development and implementation within the obstetrical-gynecological services of advanced complex preventive examination technology for women in different age groups". Two guidelines approved: "Tools and procedures for taking sampes for cytological testing for preventive purposes", 2009, and "Early diagnostic methodology for tumors of reproductive system for pregnant women", 2010.

Guidelines on "Organization and implementation of complex preventive examinations for the early detection of new growths in the female reproductive system".

Screening for breast cancer in Belarus

Aspects to be reflected in the baseline analysis.

1. Population of Belarus	9 503 807
Of them women (01.09.2010)	5 083 768
Of them aged 50-69	1 215 697
2. Life expectance	76.4 years
3. Rural to urban ratio of female population aged 50-69	
Urban	911 119
Rural	304 498

Health care and breast cancer screening

1. Annual breast cancer incidence (absolute numbers)	3700
2. Breast cancer incidence per 100 000 female population (2009)	72.4
3. Breast cancer mortality per 100 000 female population (2009)	22.8
4. % of breast cancer patients registered 5 and more years ago	59.2%
5. Number of mammographs	23
6. Number of mammographs required for screening	42
Of them mobile stations	21
7. Number of specialist radiologists required for screening (checking 5000 and more images per year)	168
8. Number of radiological lab workers required for screening	84
9. Operating cancer register	exists
10. Presence and availability of quality standards for diagnostics and treatment of breast cancer (Decree # 80 of Ministry of Health of Belarus of 09.02.2007)	exist
11. Presence of specifically trained and qualified technical staff for the quality control of screening required number	42
12. Presence of experienced morphologists (in oncological dispensaries, in autopsy facilities)	exist
13. Need for personnel responsible for coordination of data collection and reporting:	

required number	42
14. Protocols for breast cancer screening	absent
Awareness raising:	
On radio, per year	about 40 times
On TV, per year	about 50 times
Publications in press;	
Book by L.A.Putyrsky and Yu.L.Putyrsky "Advice of mammologist – how to keep your breast healthy" (2010) [Л.А. Путырский, Ю.А. Путырский, Советы врача-маммолога: как сохранить грудь здоровой].	
Leaflets, posters and brochures for the public	
Website: www.doktor.by	
Implemented by: policlinics, hospitals, N.N. Alexandrov National research hospital of oncology and medical radiology.	
15. Computers needed to develop, maintain and update databases	42

QUESTIONS FOR PREPARATION OF PLANNING OF BREAST CANCER SCREENING IN BELARUS

NB! *Prophylactic examination* in this document means medical examinations of healthy people as conducted in Belarus. *Breast cancer screening* in this document means mammographic examination of healthy (asymptomatic) women.

1. Legislation: Edicts, Decrees, Laws, Ordinances, Directives, Orders and other acts; Policies and Guidelines concerning early detection of breast cancer [prophylactic examinations]

[Указы, Декреты Президента Республики Беларусь в области здравоохранения;
Законы РБ в области здравоохранения;
Постановления Совета Министров РБ в области здравоохранения;
Постановления, Приказы и иные акты Министерства здравоохранения РБ]

1.1. What do the legislation and the current clinical practice guidelines state for the following?
   1.1.1. Age to initiate prophylactic examinations:
   1.1.2. Target age group for prophylactic examinations:
   1.1.3. Coverage: what percentage of women (by 5-year age groups) are covered by prophylactic examinations?
   1.1.4. Interval between prophylactic examinations:
   1.1.5. Screening tests used for prophylactic examinations:
   1.1.6. Standard terminology for reporting screening results:
   1.1.7. Which health professionals are permitted/obliged to conduct the prophylactic examinations?
   1.1.8. Are all of the above included in the Comprehensive National program of prevention, diagnosis and treatment of oncological diseases or another national policy?
   1.1.9. What is written specifically concerning breast cancer screening or prophylactic examinations in the Comprehensive National program of prevention, diagnosis and treatment of oncological diseases 2010-2014?

2. Current practices with asymptomatic women

In the absence of a population-based mammography screening programme, the mean breast cancer incidence from 2005 to 2009 has been about 3600 cases per year (steadily increasing from 3398 to 3773 during this period).

2.1. What is the estimated coverage of opportunistic mammography screening (i.e. how many asymptomatic women in the envisaged target population attend mammography, either private or public)? Please show data by year and in 5-year age groups if possible (under 40; 40-44; 45-49; 50-54; 55-59; 60-64; 65-69; 70+)
   - In absolute numbers
   - In percentages of resident women

2.2. How many of these breast cancer cases were detected in prophylactic examinations [профилактический осмотр] each year? Please show data in 5-year age groups if possible (under 40; 40-44; 45-49; 50-54; 55-59; 60-64; 65-69; 70+)

2.3. Please estimate how many cases were detected by opportunistic screening mammography [скрининговой маммографии] each year? Please show data in 5-year age groups if possible (under 40; 40-44; 45-49; 50-54; 55-59; 60-64; 65-69; 70+)

2.4. What is the cost to the woman for a mammographic examination?

- In the private sector
- In the public sector

3. Assessment of breast cancer incidence and mortality (please show tables, data by year starting from 1990 and by age group)

3.1. Please show breast cancer incidence data by 5-year age groups

3.1.1. Absolute numbers
3.1.2. Distribution by stage
3.1.3. Incidence rate per 100 000 (crude and age adjusted separately)

3.2. Please show breast cancer mortality data by 5-year age groups

3.2.1. Absolute numbers
3.2.2. Mortality rate per 100 000 (crude and age adjusted separately)

4. Description of breast cancer diagnostics and treatment [use 2009 or 2010 data if available]

4.1. Describe the organizational structure and geographical distribution of medical institutions involved in breast cancer early-diagnosis and treatment.

4.2. Describe the current patient pathway for a woman diagnosed with a small breast lump.

4.3. How many women diagnosed with breast cancer had a preoperative cytological diagnosis? (Absolute number and % of total)

4.4. How many women diagnosed with breast cancer had a preoperative histological diagnosis (core biopsy)? (Absolute number and % of total)

4.5. How many women operated for breast cancer had breast conserving surgery? (Absolute number and % of total)

4.6. How many women operated for breast cancer received adjuvant chemotherapy? (Absolute number and % of total)

4.7. How many women operated for breast cancer received postoperative radiotherapy? (Absolute number and % of total)

4.8. How many breast cancer patients have their treatment individually planned in a multidisciplinary team meeting? (Absolute number and % of total)

4.9. How is follow-up of breast cancer patients organised? (After operation and possible adjuvant chemotherapy and radiotherapy?)
- 4.9.1. Who follows up? (surgeon/oncologist/GP/primary care doctor/nurse)
- 4.9.2. What is the follow-up scheme for women with medium/low risk of recurrence (interval, examinations, total duration of follow-up)
- 4.9.3. Are there protocols for follow-up of women with high risk?

5. Resources for breast cancer prevention, diagnosis and treatment: premises, equipment, manpower, informatics

5.1. What facilities for early diagnostics of breast cancer exist: how many centres/units, what is the geographical distribution and what size population does each one serve?

- National level oncology hospital with a multidisciplinary team for breast cancer treatment
- Regional (область) oncological dispensaries/hospitals (Brest, Grodno, Gomel, Mogilev, Vitebsk)
- Minsk city oncological dispensary, other cities?
- District hospitals [районная больница]:
- Ambulatory care/outpatient units:
- Private sector: mammography
- Others (e.g. departmental = Ведомственные)

5.2. Equipment:

5.2.1. Mammography machines
- How many in the public sector, what % digital?
- How many in the private sector what % digital?
- Distribution by regions (область)?
- Manufacturer, model and year of production for each in table form.

5.2.2 Ultrasound machines
- How many in the public sector?
- How many in the private sector?
- Distribution by regions (область)?
- Manufacturer, model and year of production for each in table form.

5.2.3. Radiotherapy facilities: how many, where?

- Linear accelerators:
- CT treatment planning simulators:
- Others (e.g. Cobalt, brachytherapy)
- Distribution by regions (область)?
- Manufacturer, model and year of production for each in table form.

5.2.4. Technical quality control of mammography machines

- Which is the responsible authority for quality control?
- Who performs the quality control?
- How many staff and which qualification (e.g. medical physicist, technician, engineer) are engaged in quality control?
- Which protocols are followed in acceptance, daily, weekly, half-yearly and yearly quality control checkups?

5.2.5. Manpower and timelines

- Are there enough (how many, distribution by region?) qualified radiology nurses, radiologists, breast care nurses, pathologists, breast surgeons, radiotherapists, physicists, oncologists and psychologists to treat the current number of breast cancer patients within the recommended timelines?
- Do the Belarusian recommended timelines differ from the ones given in European guidelines and if they do, how?

6. Assessment of pathology service

6.1. How many pathology laboratories that examine breast cytology/histology are there in the country? Distribution by region (область)?

6.2. How many breast cytology tests and breast histology tests does each laboratory process on average each year?

6.3. How many laboratories have a pathologist specialised in breast cancer?

7. Assessment of information systems

7.1. Is there a unique personal identifier in general use for health data? If so, is this a health system number or other personal identifier?

7.2. What process (log book, filing system, or computer system) is used to register information on breast cancer patients?

7.3. Are there standard reporting forms for prophylactic examinations, for diagnosis, and for treatment services?

7.4. Does the program [we can say cancer registry for the time being as long as there is no program] have access to the population registry for its target population?

8. Preparedness to move towards a population-based mammography screening along the European guidelines

8.1. Is there a consensus among the high level health care decision makers?

8.2. Is there a consensus among the medical community?

8.3. How many women will attend screening if invited by a personal letter?

9. Contact persons

Who is responsible for the planning of population-based mammography screening?

- Chief epidemiologist: name, contact details
- Chief radiologist: name, contact details
- Chief breast surgeon: name, contact details
- Chief pathologist: name, contact details

10. Potential conditions for/against screening?

QUESTIONS FOR PREPARATION OF PLANNING OF BREAST CANCER SCREENING IN BELARUS

1. **Legislation: Edicts, Decrees, Laws, Ordinances, Directives, Orders and other acts; Policies and Guidelines concerning early detection of breast cancer [prophylactic examinations]**
   http://minzdrav.gov.by/ru/

1.1 What do the legislation and the current clinical practice guidelines state for the following?
1.1.1. Age to initiate prophylactic examinations:
– under 40 years - according to the results of the ultrasonic scanning of breasts, over 50 years - mammography is conducted once, after that - according to individual indications (decree of the MoH of Belarus of 2006)

1.1.2. Target age group for prophylactic examinations:
– under 40 years - according to the results of the ultrasonic scanning of breasts, over 50 years - mammography is conducted once, after that - according to individual indications

1.1.3. Coverage: what percentage of women (by 5-year age groups) are covered by prophylactic examinations:
– 90% of all women are checked-up by gynecologists (breasts are always assessed)

1.1.4. Interval between prophylactic examinations:
- once a year

1.1.5. Screening tests used for prophylactic examinations:
– not used

1.1.6. Which health professionals are permitted/obliged to conduct the prophylactic examinations?
– Therapists in policlinic, GP, oncologist, obstetrician-gynecologist

1.1.7. Are all of the above included in the Comprehensive National program of prevention, diagnosis and treatment of oncological diseases or another national policy?
– inclusion in process: mammography screening program developed and is being discussed

1.1.8. What is written specifically concerning breast cancer screening or prophylactic examinations in the Comprehensive National program of prevention, diagnosis and treatment of oncological diseases 2010-2014?
– mammography screening program has been developed and is being reviewed by the Ministry of health

2. Current practices with asymptomatic women
In the absence of a population-based mammography screening program, the mean breast cancer incidence from 2005 to 2009 has been about 3600 cases per year (steadily increasing from 3398 to 3773 during this period).

2.1. What is the estimated coverage of opportunistic mammography screening (i.e. how many asymptomatic women in the envisaged target population attend mammography, either private or public)? Please show data by year and in 5-year age groups if possible (under 40; 40-44; 45-49; 50-54; 55-59; 60-64; 65-69; 70+)

- In absolute numbers
- In percentages of resident women

– In the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, about 4000 mammograms are conducted every year, of which about 20% for the women under 45, and about 80% - for those over 45.

2.2. How many of these breast cancer cases were detected in prophylactic examinations [профилактический осмотр] each year? Please show data in 5-year age groups if possible (under 40; 40-44; 45-49; 50-54; 55-59; 60-64; 65-69; 70+)
– see Annex 1

2.3. Please estimate how many cases were detected by opportunistic screening mammography each year? Please show data in 5-year age groups if possible (under 40; 40-44; 45-49; 50-54; 55-59; 60-64; 65-69; 70+)
– no information

2.4. What is the cost to the woman for a mammographic examination?

- In the private sector: **70 000 roubles**
- In the public sector: **35 000 –40 000 roubles (1USD = 3000 roubles)**

3. Assessment of breast cancer incidence and mortality (please show tables, data by year starting from 1990 and by age group)

3.1. Please show breast cancer incidence data by 5-year age groups
3.1.1. Absolute numbers
3.1.2. Distribution by stage
3.1.3 Incidence rate per 100 000 (crude and age adjusted separately)
– see Annex 1, 2 and 3

3.2. Please show breast cancer mortality data by 5-year age groups
3.2.1. Absolute numbers
3.2.2. Mortality rate per 100 000 (crude and age adjusted separately)
– see Annex 4

4. Description of breast cancer diagnostics and treatment [use 2009 or 2010 data if available]
4.1. Describe the organizational structure and geographical distribution of medical institutions involved in breast cancer early-diagnosis and treatment.

– In the N.N. Aleksandrov research centre and clinic for oncology and medical radiology and in all other oncological facilities of Belarus early detection and care for breast cancer is provided; oncological clinics are located in all regional centres of the country.

4.2. Describe the current patient pathway for a woman diagnosed with a small breast lump.
PHC doctor – oncologist (or surgeon, gynecologist, or therapist) of the local health facility - specialized oncological facility

4.3. How many women diagnosed with breast cancer had a preoperative cytological diagnosis? (Absolute number and % of total)
– about 90% of women diagnosed with breast cancer undergo pre-surgical cytological assessment (surgery is not possible without morphological verification; if it is not possible to establish the diagnosis cytologycally, histological assessment is conducted)

4.4. How many women diagnosed with breast cancer had a preoperative histological diagnosis (core biopsy)? (Absolute number and % of total)
– about 30% of women diagnosed with breast cancer undergo pre-surgical cytological assessment (surgery is not possible without morphological verification; if it is not possible to establish the diagnosis cytologycally, histological assessment is conducted)

4.5. How many women operated for breast cancer had breast conserving surgery? (Absolute number and % of total)
– In 2010, in the N.N. Aleksandrov research centre and clinic for oncology and medical radiology 1308 women with breast cancer received surgical interventions, of them 199 (12.5%) received breast conserving surgery, and 39 women received complex (with primary reconstruction) breast conserving surgery

4.6. How many women operated for breast cancer received adjuvant chemotherapy? (Absolute number and % of total)
– adjuvant chemotherapy was provided to 1100 women (84%)

4.7. How many women operated for breast cancer received postoperative radiotherapy? (Absolute number and % of total)
– postoperative radiotherapy was provided to 730 women (56%)

4.8. How many breast cancer patients have their treatment individually planned in a multidisciplinary team meeting? (Absolute number and % of total)

– In the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, 16-20 surgeries for breast cancer are planned every week

4.9. How is follow-up of breast cancer patients organised? (After operation and possible adjuvant chemotherapy and radiotherapy?)
– follow-up of breast cancer patients is organized

4.9.1. Who follows up? (surgeon/oncologist/GP/primary care doctor/nurse)
– follow-up is provided by oncologist

4.9.2. What is the follow-up scheme for women with medium/low risk of recurrence (interval, examinations, i.e., mammography, ultrasonic examination, blood testing; total duration of follow-up in years)
– after specialized care, during the first 2 years patients are assessed every 3 months, during the third year - every 4 months, during years 4 and 5 - once in 6 months, after that - once a year; every time the patient is assessed by oncologist and oncogynecologist; once a year, X-ray examination of lungs is conducted; in case of breast conserving surgery, bilateral mammography is conducted once in 1-2 years; after mastectomy, mammographic assessment of the other breast is conducted once in 1-2 years; abdominal cavity X-ray examination is conducted once in 6 months (during first 3 years), after that - once a year. Scintigraphic examination of the skeleton is conducted once in 1-2 years (Decree of MoH #80).

4.9.3. Are there protocols for follow-up of women with high risk?
– yes

5. Resources for breast cancer prevention, diagnosis and treatment: premises, equipment, manpower, informatics

5.1. What facilities for early diagnostics of breast cancer exist: how many centres/units, what is the geographical distribution and what size population does each one serve?

- National level oncology hospital with a multidisciplinary team for breast cancer treatment
- Regional oncological dispensaries/hospitals (Brest, Grodno, Gomel, Mogilev, Vitebsk)
- Minsk city oncological dispensary, other cities?
- District hospitals:
- Ambulatory care/outpatient units:
- Private sector: mammography
- Others (e.g. departmental)

5.2. Equipment:
5.2.1. Mammography machines

- How many in the public sector, what % digital?
- How many in the private sector what % digital?
- Distribution by regions?
- Manufacturer, model and year of production for each in table form.

– see Annex 5

5.2.2. Ultrasound machines

- How many in the public sector?
- How many in the private sector?
- Distribution by regions?
- Manufacturer, model and year of production for each in table form.

– no information

5.2.3. Radiotherapy facilities: how many, where?

- Linear accelerators:
- CT treatment planning simulators:
- Others (e.g. Cobalt, brachytherapy)
- Distribution by regions?
- Manufacturer, model and year of production for each in table form.

– oncological facilities of Belarus are equipped with 8 linear accelerators, 15 CT simulators for radiotherapy planning, 24 Cobalt gamma ray installations and 15 installations for brachytherapy

See Annex 6

5.2.4. Technical quality control of mammography machines

- Which is the responsible authority for quality control?

• Who performs the quality control?

• How many staff and which qualification (e.g. medical physicist, technician, engineer) are engaged in quality control?

• Which protocols are followed in acceptance, daily, weekly, half-yearly and yearly quality control checkups?

– there is a decree of MoH on quality control for the film mammography machines; currently, similar decree is being drafted for digital mammographic machines

5.2.5. Manpower and timelines

• Are there enough (how many, distribution by region?) qualified radiology nurses, radiologists, breast care nurses, pathologists, breast surgeons, radiotherapists, physicists, oncologists and psychologists to treat the current number of breast cancer patients within the recommended timelines?

– currently, various specialists are trained to conduct mammography screening in Belarus

• Do the Belarusian recommended timelines differ from the ones given in European guidelines and if they do, how?

– do not differ (are fully harmonized)

6. Assessment of pathology service

6.1. How many pathology laboratories that examine breast cytology/histology are there in the country? Distribution by region?

– there are morphology units; at every unit there is an oncomorphology department responsible for the morphologic diagnostic (cytological, histological examination, detection of the level of expression of receptors to hormones, and of the second type epidermal growth factor) in breast cancer cases

6.2. How many breast cytology tests and breast histology tests does each laboratory process on average each year?

– In 2010, in the N.N. Aleksandrov research centre and clinic for oncology and medical radiology about 1400 histological examinations of breast cancer cases were conducted

6.3. How many laboratories have a pathologist specialised in breast cancer?

– In the N.N. Aleksandrov research centre and clinic for oncology and medical radiology and in every regional oncomorphology department there is a pathologist specializing in breast cancer

7. Assessment of information systems

7.1. Is there a unique personal identifier in general use for health data? If so, is this a health system number or other personal identifier?

– breast cancer is coded as C.50 as in ICD; for screening purposes, there are plans to introduce the code of "passport number of the patient"

7.2. What process (log book, filing system, or computer system) is used to register information on breast cancer patients?

– computer system

7.3. Are there standard reporting forms for prophylactic examinations, for diagnosis, and for treatment services?
– yes

7.4. Does the program [we can say cancer registry for the time being as long as there is no program] have access to the population registry for its target population?

– program for access to the population registries is in development

8. Preparedness to move towards a population-based mammography screening along the European guidelines

8.1. Is there a consensus among the high level health care decision makers?
– yes

8.2. Is there a consensus among the medical community?
– yes

8.3. How many women will attend screening if invited by a personal letter?
– about 80%

9. Contact persons

Who is responsible for the planning of population-based mammography screening?

- Координаторы от Министерства здравоохранения Республики Беларусь

– Valery Asimovich Hodjaev, First Deputy Minister of Health of Belarus: tel. +375 17 222 68 97,
– Tatiana Fiodorovna Migal, Deputy Head of the Department of Health Services, Head of the Specialized Health Services Unit of the Ministry of Health of Belarus, tel. +375 291 79 04 96

- Chief epidemiologist: name, contact details:

–**Yury Ivanovich Averkin, candidate in medical sciences, Head of the Cancer Epidemiology Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel.:+375 17 265 39 21**
– Pavel Ivanovich Moiseev, candidate in medical sciences, Head of the Cancer Control Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel.+375 17 265 36 80

- Chief radiologist: name, contact details:

– Georgiy Vasilievich Chizh, Chief radiologist of the Ministry of Health of Belarus, tel. +375 17 222 67 63
– Irina Ivanovna Minaylo, candidate in medical sciences, Head of the Radiotherapy Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel. +375 296 69 16 12

- Chief breast surgeon: name, contact details

– Leonid Alekseevich Putyrski, MD, professor, Head of the Oncomammology Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel. + 375 17 265 95 28,
– Irina Nikolayevna Antonenkova, MD, chief research fellow of the Oncomammology Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel. +375 296 84 73 80

- Chief pathologist: name, contact details

– Aleksandr Cheslavovich Dubrovski, candidate in medical sciences, Head of the Pathology and Anatomy Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel. +375 297 08 11 50,
– Oksana Alekseevna Yerokhina, candidate in medical sciences, cytologist of the Pathology and Anatomy Department of the N.N. Aleksandrov research centre and clinic for oncology and medical radiology, tel. +375 296 61 61 03
- Alexandr Nikolaevich Barsukov, Chief Obstetrician and Gynaecologist of MoH +375 17 222 66 30

10. Potential conditions for/against screening?

– for screening: high incidence of breast cancer, see Annex 1

ATTACHMENT 1: Age-specific incidence rates of malignant BREAST neoplasms in Belarus

Year	Total per 100 000	INCIDENCE IN AGE GROUP (YEARS)																	
		0	1-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+
2000	27.7						0.3	0.9	8.5	18.3	32.5	51.4	63.7	55.3	68.6	70.3	74.1	83.8	70.3	44.0
2001	28.9						0.4	2.2	8.0	18.2	35.0	50.6	61.3	61.1	75.8	66.5	78.7	85.8	72.6	48.3
2002	30.7					0.1	0.9	2.4	8.7	16.4	36.7	55.4	65.7	70.4	77.2	76.4	79.3	79.5	78.0	43.5
2003	32.9						0.5	1.0	5.8	19.6	41.2	59.1	60.4	84.1	80.2	84.0	82.2	84.0	87.1	68.1
2004	35.3						0.3	3.1	9.5	19.3	39.0	59.3	61.7	89.6	93.2	93.5	85.4	87.7	108.8	60.5
2005	34.6						0.2	1.5	8.6	18.4	33.5	54.5	66.1	80.1	91.1	95.2	82.9	99.8	94.9	72.2
2006	35.1					0.1	0.2	1.9	6.8	19.0	35.0	54.6	68.8	84.4	82.5	91.8	93.8	93.1	98.5	56.3
2007	37.4						0.1	1.5	8.0	19.5	34.3	56.2	66.8	85.6	102.5	105.6	99.9	99.7	97.2	77.2
2008	38.0					0.1	0.6	3.4	6.4	20.2	36.4	52.0	70.5	76.6	96.7	104.3	103.5	105.7	118.9	92.9
2009	38.9						0.5	2.3	9.2	20.9	38.0	56.9	70.2	77.2	107.0	98.9	111.4	101.6	96.5	84.5

ATTACHMENT 2: Age distribution of newly diagnosed cases of malignant BREAST neoplasms in Belarus																				
Year	Number of newly diagnosed cases	By age group (years)																		
		0	1-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+
2000	2774	0	0	0	0	0	2	6	59	150	268	355	341	239	393	334	315	203	68	41
2001	2886	0	0	0	0	0	3	15	55	143	295	357	364	236	428	303	346	223	75	43
2002	3057	0	0	0	0	1	7	17	59	124	312	403	413	261	417	357	341	225	84	36
2003	3252	0	0	0	0	0	4	7	40	142	349	442	390	331	397	391	354	245	109	51
2004	3474	0	0	0	0	0	2	22	65	135	323	464	403	396	402	452	344	271	150	45
2005	3388	0	0	0	0	0	2	11	59	125	269	435	434	399	352	472	319	314	145	52
2006	3419	0	0	0	0	1	2	14	47	128	269	446	461	466	284	448	346	303	162	42
2007	3638	0	0	0	0	0	1	11	55	131	253	462	462	500	340	493	380	317	175	58
2008	3685	0	0	0	0	1	5	26	44	136	258	426	503	461	343	447	396	339	223	77
2009	3758	0	0	0	0	0	4	18	64	140	260	457	524	471	428	370	445	306	194	77
TOTAL	**33331**	**0**	**0**	**0**	**0**	**3**	**32**	**147**	**547**	**1354**	**2856**	**4247**	**4295**	**3760**	**3784**	**4067**	**3586**	**2746**	**1385**	**522**

ATTACHMENT 3: Age-specific mortality rates of malignant BREAST neoplasms in Belarus

Year	Total per 100 000	MORTALITY IN AGE GROUP (YEARS)																		
		0	1-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85+
1990	11.0							0.5	1.5	5.3	11.5	17.0	20.6	25.1	31.5	39.5	39.7	48.4	36.2	36.1
1991	10.7						0.1	0.1	1.8	5.5	10.9	12.4	21.6	26.0	28.0	42.0	43.9	37.1	41.4	29.8
1992	12.0							0.4	3.2	6.1	9.4	20.9	21.7	28.1	29.3	39.6	53.9	49.0	49.5	44.1
1993	12.1						0.1	0.8	2.2	5.4	11.6	17.8	20.1	29.2	27.9	40.8	51.2	54.6	49.3	56.8
1994	12.5						0.1	0.7	1.5	5.0	9.2	21.4	24.7	32.4	30.9	40.4	49.9	52.7	41.1	49.4
1995	13.1							0.3	2.0	3.9	9.1	18.9	24.7	31.0	32.5	41.4	52.0	71.6	56.6	54.3
1996	12.8						0.1	0.9	1.9	4.5	9.7	16.1	23.9	28.4	32.7	35.9	56.8	71.6	49.2	51.6
1997	13.0							0.7	1.7	5.2	12.2	15.5	21.4	29.6	33.3	36.5	49.2	67.7	64.2	55.1
1998	13.4								2.4	4.6	11.5	17.6	25.5	26.8	36.0	35.2	55.2	66.1	58.8	50.1
1999	14.6							0.4	2.0	3.6	10.8	18.4	30.6	32.5	37.3	40.0	51.4	70.2	77.8	60.3
2000	14.6						0.3	0.4	1.9	4.9	9.7	19.6	27.1	28.5	35.6	36.8	55.1	69.4	65.1	81.6
2001	13.7							0.3	1.3	3.6	8.9	14.0	23.9	28.7	31.9	44.1	48.9	68.5	63.9	65.1
2002	13.5							0.3	0.6	3.2	7.8	15.5	24.3	21.3	35.8	39.6	51.4	57.3	85.5	65.3
2003	14.1						0.1	0.6	2.2	4.7	9.6	15.5	24.5	34.1	30.7	43.6	42.9	60.7	69.5	61.4
2004	12.9							0.7	0.9	3.9	9.0	14.7	18.8	31.7	32.9	41.0	39.7	47.9	60.9	59.2
2005	13.1							0.6	1.6	4.0	7.2	13.3	23.8	34.3	31.6	40.3	36.1	51.2	60.2	54.1
2006	12.8						0.1	0.7	1.2	4.0	7.5	12.5	19.2	27.7	36.9	39.3	43.1	43.3	57.8	64.4
2007	14.2							0.3	1.0	5.1	7.3	15.0	22.3	33.7	44.0	44.6	39.2	44.7	60.5	66.6
2008	12.8							0.3	1.5	4.5	7.1	13.3	22.3	29.2	36.4	34.3	42.6	45.8	45.3	45.9
2009	12.3							0.4	1.0	2.7	7.2	11.2	19.0	26.7	42.8	39.3	39.8	40.8	39.8	43.9

Attachment 4: Stage distribution of newly diagnosed malignant Breast neoplasms in Belarus

Year	Number of newly diagnosed cases	From them with known stage		DISTRIBUTION BY STAGE								Stage unknown	
				I		II		III		IV			
		number	%	number	%	number	%	number	%	number	%	number	%
2000	2774	2751	99.2	429	15.5	1590	57.3	479	17.3	253	9.1	23	0.8
2001	2886	2867	99.3	492	17.0	1590	55.1	537	18.6	248	8.6	19	0.7
2002	3057	3036	99.3	540	17.7	1727	56.5	497	16.3	272	8.9	21	0.7
2003	3252	3230	99.3	604	18.6	1940	59.7	452	13.9	234	7.2	22	0.7
2004	3474	3447	99.2	694	20.0	1940	55.8	596	17.2	217	6.2	27	0.8
2005	3388	3380	99.8	687	20.3	1758	51.9	720	21.3	215	6.3	8	0.2
2006	3419	3395	99.3	711	20.8	1724	50.4	726	21.2	234	6.8	24	0.7
2007	3638	3598	98.9	873	24.0	1804	49.6	702	19.3	219	6.0	40	1.1
2008	3685	3670	99.6	964	26.2	1892	51.3	637	17.3	177	4.8	15	0.4
2009	3758	3736	99.4	881	23.4	2027	53.9	644	17.1	184	4.9	22	0.6
TOTAL	**33331**	**33110**	**99.3**	**6875**	**20.6**	**17992**	**54**	**5990**	**18.0**	**2253**	**6.8**	**221**	**0.7**

ANNEX 5

Table 5. Mammography equipment in health care facilities of Belarus

Current equipment

№	Health care facility	Type	Maker	Model year	Notes
	National facilities				
1.	Oncology and medical radiology research center and hospital	Mammomat- 3000	Siemens (Germany)	1997	
2.	Oncology and medical radiology research center and hospital	Mammomat- 3000	Siemens (Germany)	2005	digital
	Minsk				
3.	Minsk city oncological clinic	Mammomat- 300 Nova	Siemens (Germany)	2001	
4.	City hospital #8	MXR-200	Listem (Korea)	2001	
5.	Policlinic #19	Melody	Villa (Italy)	2005	
6.	Policlinic #14	Mammoscan	Adani (Belarus)	2009	digital
7.	Policlinic #17	Mammoscan	Adani (Belarus)	2009	digital
8.	Policlinic #3	Mammoscan	Adani (Belarus)	2009	digital
9.	Policlinic #6	Mammoscan	Adani (Belarus)	2010	digital
10.	Policlinic #12	Mammoscan	Adani (Belarus)	2010	digital
11.	Policlinic #26	Mammoscan	Adani (Belarus)	20010	digital
12.	Policlinic #34	Mammoscan	Adani (Belarus)	2010	digital
13.	Centre for consultations and diagnostics	Mammoscan	Adani (Belarus)	2010	digital
	Minsk region				
14.	Regional maternity hospital	Melody	Villa (Italy)	2006	
15.	Nesvizh central district hospital	Mammoscan	Adani (Belarus)	2009	digital
16.	Borisov maternity hospital	Mammoscan	Adani (Belarus)	2009	digital
17.	Soligorsk central district hospital	Mammoscan	Adani (Belarus)	2009	digital
18.	Molodechno maternity hospital	Mammoscan	Adani (Belarus)	2009	digital
	Brest region				
19.	Brest regional	Melody	Villa (Italy)	2006	

	oncological clinic				
20.	Pinsk inter-district oncological clinic	Melody	Villa (Italy)	2005	
	Vitebsk region				
21.	Vitebsk regional oncological clinic	Melody	Villa (Italy)	2000	
	Gomel region				
22.	Gomel regional oncological clinic	Mammodiagnost UC	Philips (Netherlands)	1994	
23.	Gomel regional oncological clinic	Sophie	Planmed (Finland)	2006	digital
24.	Gomel city central policlinic	Mammoscan	Adani (Belarus)	2009	digital
	Grodno region				
25.	Grodno regional hospital	Melody	Villa (Italy)	2005	
26.	Grodno city central policlinic	Mammoexpress	Adani (Belarus)	2009	digital
27.	Lida central district hospital	Mammoexpress	Adani (Belarus)	2009	digital
	Mogilev region				
28.	Mogilev regional oncological clinic	Melody	Villa (Italy)	2005	
29.	Bobruisk city oncological clinic	Mammomat- 3000	Siemens (Germany)	2001	

+20 Mammoscan installations purchased by the Ministry of Health

Planned

Health care facility	Name	Notes
Brest region		
Brest city central policlinic	Mammoscan	Request of Department of health of Brest regional executive committee
Pinsk city central policlinic	Mammoscan	Request of Department of health of Brest regional executive committee
Baranovichi oncological clinic	Mammoscan	Request of Department of health of Brest regional executive committee
Baranovichi city central policlinic	Mammoscan	Request of Department of health of Brest regional executive committee
Vitebsk region		
Vitebsk regional diagnostic centre	Mammoscan	Request of Department of health of Vitebsk regional executive committee
Orsha city central policlinic поликлиника	Mammoscan	Request of Department of health of Vitebsk regional executive committee

Glubokoe cetral district hospital	Mammoscan	Request of Department of health of Vitebsk regional executive committee
Gomel region		
Gomel city central policlinic	Mammoscan	Request of Department of health of Gomel regional executive committee
Mozyr oncological clinic	Mammoscan	Request of Department of health of Gomel regional executive committee
Svetlogorsk central district hospital	Mammoscan	Request of Department of health of Gomel regional executive committee
Rechitsa central district hospital	Mammoscan	Request of Department of health of Gomel regional executive committee
Grodno region		
Oshmyany central district hospital	Mammoscan	Request of Department of health of Grodno regional executive committee
Slonim central district hospital	Mammoscan	Request of Department of health of Grodno regional executive committee
Grodno city central policlinic (building # 1)	Mammoscan	Request of Department of health of Grodno regional executive committee
Minsk region		
Maryina Gorka central district hospital	Mammoscan	Request of Department of health of Minsk regional executive committee
Slutsk central district hospital	Mammoscan	Request of Department of health of Minsk regional executive committee
Zhodino city central hospital	Mammoscan	Request of Department of health of Minsk regional executive committee
Mogilev region		
Mogilev regional treatment and diagnostic centre	Mammoscan	Request of Department of health of Mogilev regional executive committee
Krichev central district hospital	Mammoscan	Request of Department of health of Mogilev regional executive committee
Bobruisk city policlinic #3	Mammoscan	Request of Department of health of Mogilev regional executive committee

ANNEX 6. Equipment for radiological therapy in the health care facilities of Belarus

№	Type	Name	Maker	In service since
		N.N. Aleksandrov Oncology and medical radiology research centre and hospital		
1	Linear accelerator	Clinac-2300C	Varian (USA)	2005
2	Linear accelerator	Mevatron KD-2	Siemens (Germany)	1996
3	Linear accelerator	Trilogy	Varian (USA)	2008
4	Gamma ray therapy installation	Rokus-AM	Russia	1992
7	Gamma ray therapy installation	Tetratron	Canada	2008
6	Gamma ray therapy installation	Agat-S (calibration dosimetry)	USSR	1985
7	Radiation therapy simulator	Acquiti	Varian (USA)	2005
8	Radiation therapy simulator	Simulix Out of service until upgrade in 2011	Nucletron (Netherlands)	1998
9	Brachytherapy installation	Microselectron HDR-old	Nucletron (Netherlands)	1990
10	Brachytherapy installation	Microselectron PDR	Nucletron (Netherlands)	1995
11	IBU Brachytherapy complex	Microselectron HDR	Nucletron (Netherlands)	2008
		Minsk regional hospital		
1	Gamma ray therapy installation	Agat-S	USSR	1976
		Vileyka city oncological clinic		

1	Gamma ray therapy installation	Agat-S	USSR	1984

Minsk city oncological clinic

1	Gamma ray therapy installation	Tetratron	Canada	2004
2	Gamma ray therapy installation	Agat-R1	Russia	1993
4	Brachytherapy installation	Microselectron HDR-new	Nucletron (Netherlands)	2000
5	Radiation therapy simulator	Simulix	Nucletron (Netherlands)	1999
6	Radiation therapy simulator	Nucletron		2010

Minsk city hospital #9

1	Gamma ray therapy installation	Agat-S	Russia	1992

Vitebsk regional oncology clinic

1	Linear accelerator	Clinac-2300C	Varian (USA)	2003
2	Gamma ray therapy installation	Teragam	Czech Republic	2003
4	Brachytherapy installation	Varisos	Varian (USA)	2002
5	Брахитерапевтический аппарат	Agat-VU	Estonia	1991
6	Radiation therapy simulator	Chematron	Varian (USA)	2002

Polotsk inter-district oncology clinic

1	Gamma ray therapy installation	Rokus-AM	Russia	2000
2	Gamma ray therapy installation	Agat-S	USSR	1988
3	Brachytherapy installation	Agat-VU	Estonia	1990

Gomel regional oncological clinic

1.	Electron linear accelerator	Electa	UK	2009
2	Gamma ray therapy installation	Rokus-AM	Russia	1992
3	Gamma ray therapy installation	Rokus-AM	Russia	1992
4	Gamma ray therapy installation	Rokus-AM	Russia	1995
5	Brachytherapy installation	Microselectron HDR-old	Nucletron (Netherlands)	1995
6	Brachytherapy installation	Agat-VU-1	Estonia	1994
7	Radiation therapy simulator	Simulix	Nucletron (Netherlands)	1997
8	Radiation therapy simulator	Mevasim	Siemens (Germany)	1994
9	CT for planning	Aquilon	Toshiba (Japan)	2009
1	2 short-focus radiotherapy installations			

Brest regional oncological clinic

1	Linear accelerator	Mevatron KD-2	Siemens (Germany)	1994
2	Gamma ray therapy installation	Rokus-AM	Russia	1996
3	Brachytherapy installation	Microselectron HDR-old	Nucletron (Netherlands)	2000
4	Brachytherapy installation	Agat-VU	Estonia	1997
5	Radiation therapy simulator	Mevasim	Siemens (Germany)	1996
6	Radiation therapy complex	Linear accelerator with planning system, CT for planning	Electa (UK)	2010

Baranovichi city oncological clinic

1	Gamma ray therapy installation	Rokus-AM	Russia	1992
2	Gamma ray therapy installation	Agat-RM	USSR	1985
4	Brachytherapy installation	Agat-VU	Estonia	1992
5	Radiation therapy simulator	Nucletron		2010

Pinsk inter-district oncological clinic

1	Gamma ray therapy installation	Rokus-AM	Russia	2001
2	Gamma ray therapy installation	Agat-S	USSR	1991

Mogilev regional oncological clinic

1	Gamma ray therapy installation	Tetratron	Canada	2007
2	Gamma ray therapy installation	Agat-S	USSR	1990
3	Brachytherapy installation	Agat-VU-1	Estonia	1992
4	Radiation therapy complex	Linear accelerator with planning system, simulator, CT for planning	Varian (USA)	2010

Bobruisk oncological clinic

1	Gamma ray therapy installation	Tetratron	Canada	2003
2	Brachytherapy installation	Microselectron HDR-old	Nucletron (Netherlands)	1996
3	Radiation therapy simulator	Mevasim	Siemens (Germany)	2002

Grodno regional hospital

1	Gamma ray therapy installation	Rokus-AM	Russia	2001
2	Gamma ray therapy installation	Agat-S	USSR	1988
3	Radiation therapy simulator	Nucletron		2010
4	IBU Brachytherapy complex	Microselectron HDR	Nucletron (Netherlands)	2010

Наименование
организации здравоохранения
_____

Приложение № 33
Приказ Министерства здравоохранения
Республики Беларусь
«_____» _____ 2006 г. №
Учетная медицинская документация
Форма №

_____
п-ка, ж.к., № исслед., год

Централизованная
цитологическая лаборатория

_____
фамилия, инициалы, возраст

_____
адрес

_____
откуда взят мазок

_____ _____
последние месячные, менопауза профосмотр, обследование

Клинически здорова, беременность _____ недель, эрозия ш.м., полип ц.к., воспаление (опухоль) придатков матки, маточное кровотечение, подозрение на рак _____

_____(чего)

Предыдущее цитологическое исследование № _____ «_____» _____

Врач

Акушерка

ЦИТОГРАММА	РЕКОМЕНДАЦИИ
Неинформативный мазок _____	Исследование повторить _____
Цитограмма без особенностей _____	Цитологический контроль после противо-
Воспалительный тип мазка _____	воспалительного лечения _____
Трихомонады, грибы, вирусное поражение _____	Углубленное обследование (кольпо- скопия, биопсия, выскабливание цервикального канала) _____
Наличие клеток эндометрия (II фаза цикла, постменопауза) _____	Повторный мазок через _____
CIN I _____	Направить в онкологический диспансер
CIN II _____	
CIN III _____	«_____» _____
Подозрение на рак _____	**Врач**

Рак _____

Лаборант

Name of
Health Organization
_____

Appendix № 33
Order of the Ministry of Health
Republic of Belarus

«_____» _____ 2006 г. №
Medical documentation for the record
Form number

_____
polyclinic, women's polyclinic, № of examination, year

Central
cytological laboratory

_____
family name, initials, age

_____
adress

_____
where was the smear taken from

_____ _____
Last period, menopause prophylactic examination, examination

Clinically healthy, pregnancy _____ weeks, cervical erosion, polyp of the cervical canal, inflammation (tumor) of adnexes, uterine bleeding, suspicion of cancer _____
_____(what)

Previous cytological examination № _____ «_____» _____

Physician

Midwife

CYTOGRAM	RECOMMENDATIONS
Uninformative smear _____	Repeat examination _____
No special features in cytogram _____	Cytological control after anti-infectious therapy
Inflammatory type smear _____	_____
Trichomonas, fungi, viral lesion _____	In-depth examination (colposcopy, biopsy, curettage of the cervical canal)
Presence of endometrial cells (II phase of cycle, postmenopause) _____	_____
CIN I _____	Repeat smear after _____
CIN II _____	Refer to oncological dispensary
CIN III _____	«_____» _____
Suspicion of cancer _____	**Physician**
Cancer_____	**Technician**

Control of Breast Cancer and Cervical Cancer in Belarus Current Status and Prospects for Future Improvement with Special Attention to Population Based Screening Programs

Seminar and Round Table 17.02.2011 Hotel IBB, Minsk

Agenda

SEMINAR

Moderation: Egor Zaitsev

9:15 Opening - Egor Zaitsev

9:20 The Health Care System in the Republic of Belarus. Main Problems and Questions - Tatiana Fiodorovna Migal

9:35 The role of breast self examination and clinical examination in early detection of breast cancer - Leonid Alekseevich Putyrski

10:05 Cervical cancer in the republic of Belarus - Tatiana Mikhailovna Litvinova

10:35 Cytological practice in medical examination of female population of the Republic of Belarus - Ludmila Borisovna Klukina

11:30 Implementation of Cancer screening in the European Union - Lawrence von Karsa

12:50 European Certification of Screening Programs (Statement) - Karin Jöns

13:18 Nationwide Mammography Screening: Major Issues associated with Introduction of the Programme - Peter Dean

13:35 About cervical cancer screening guidelines - Eero Suonio

ROUND TABLE

Moderation: Egor Zaitsev and Lawrence von Karsa
Participants – all attending national and WHO/IARC experts

15:40 Screening of cervical cancer – discussion points

- Proposal to switch to population based screening
- Proposal to add colposcopy to cytological screening
- Proposal to screen from 20 to 60 years
- Proposal to change stain from Pappenheim to Papanicolau
- Proposal to increase screening interval to 3-5 years
- Proposal to use the Bethesda classification

ROUND TABLE, cont'd

16:10 Screening of Breast cancer – discussion points

- Proposal to have digital mammography screening
- Proposal to screen women 50-69 years of age
- Proposal to do two (craniocaudal and mediolateral oblique) projections
- Proposal to have a screening interval of 2 years
- Proposal to perform monitoring, diagnosis and therapy in multidisciplinary team
- The same diagnostic specialist should perform all diagnostic examinations: ultrasound, reading of mammography, breast biopsy and preoperative MRI.

17:35 Consensus conclusions

Moderation - Egor Zaitsev and Valentin Rusovich
Participants – All attending national and WHO/IARC experts

List of participants

N.N. Antonenkava – Chief Scientist, Department of Oncomammology, Alexandrov Research Centre and Oncology Clinic

Yuri Averkin – Head, Department of Cancer Epidemiology

G.V. Chiz – Chief Radiologist, Ministry of Health

P. Dean, Radiololologist, University of Turku

O.A. Erokhina – Physician-cytologist, Chief Supernumerary Specialist on Cytology, Ministry of Health

A.T. Ilkevich – Physician, Department of Radiation Diagnostics

Vera Ilyenkova - National Professional Officer, Belarus country office, Minsk

K. Joens - Senior advisor, Brussels

V.V. Klimov – Head, Foreign Relations Sector, Ministry of Health

L.B. Klukina – Professor

G. Kostevich – Scientist, Oncologist, Obstetrician-Gynaecologist

S.A. Krasnyi – Deputy Research Director

V.I. Kuziur – Chief Nurse, Polyclinic No 34

T.M. Litvinova – Chief Scientist, Department of Oncogynaecological Pathology, Alexandrov Research Centre and Oncology Clinic

T.F. Migal - Deputy Head, Department of Health Care Organization, Ministry of Health

T.I. Nabebina – Physician-Pathologist, Alexandrov Research Centre and Oncology Clinic V. Rusovich - National Professional Officer, WHO country office Belarus

D.I. Shevtsov – Chief Physician, Polyclinic No 34

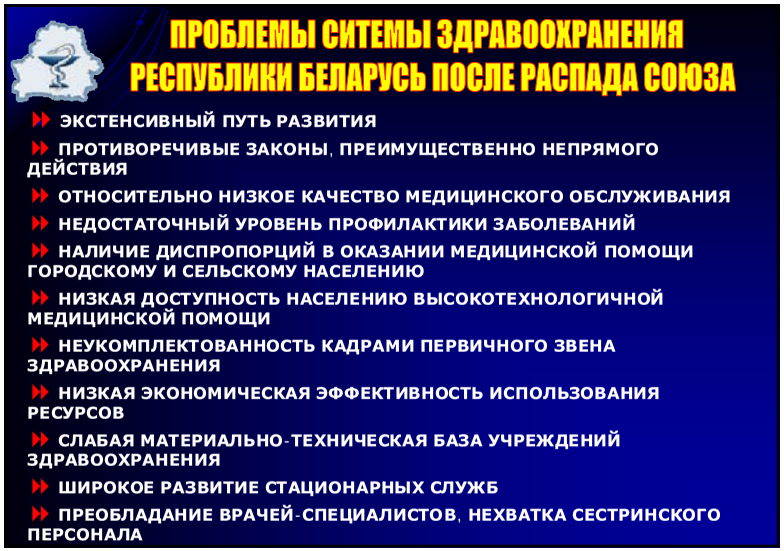
E. Suonio – Oncologist, Visiting scientist, IARC

L. von Karsa - Physician and quality assurance specialist, IARC

E. Zaitsev - Head of WHO country office, Belarus


СИСТЕМА ЗДРАВООХРАНЕНИЯ
В РЕСПУБЛИКЕ БЕЛАРУСЬ.
ОСНОВНЫЕ ПРОБЛЕМЫ, ВОПРОСЫ.
г.Минск 2011 г.
МИГАЛЬ Т.Ф.
ЗАМЕСТИТЕЛЬ НАЧАЛЬНИКА УПРАВЛЕНИЯ
ОРГАНИЗАЦИИ МЕДИЦИНСКОЙ ПОМОЩИ
МИНИСТЕРСТВА ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ


ЗДОРОВЬЕ НАЦИИ – ЭТО ВЫСШАЯ ЦЕННОСТЬ ГОСУДАРСТВА
ЗДОРОВЬЕ ЧЕЛОВЕКА – ЭТО ОДИН ИЗ ВАЖНЕЙШИХ ПРИОРИТЕТОВ НАШЕЙ ГОСУДАРСТВЕННОЙ ПОЛИТИКИ
ОСНОВОПОЛАГАЮЩИЕ ПРИНЦИПЫ БЕЛОРУССКОГО ЗДРАВООХРАНЕНИЯ – СОБЛЮДЕНИЕ СОЦИАЛЬНОЙ СПРАВЕДЛИВОСТИ И ВСЕОБЩИЙ ОХВАТ НАСЕЛЕНИЯ БЕСПЛАТНОЙ МЕДИЦИНСКОЙ ПОМОЩЬЮ, ПРЕДОСТАВЛЯЕМОЙ ЗА СЧЕТ СРЕДСТВ РЕСПУБЛИКАНСКОГО И МЕСТНЫХ БЮДЖЕТОВ


ПРОБЛЕМЫ СИТЕМЫ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ ПОСЛЕ РАСПАДА СОЮЗА
ЭКСТЕНСИВНЫЙ ПУТЬ РАЗВИТИЯ
ПРОТИВОРЕЧИВЫЕ ЗАКОНЫ, ПРЕИМУЩЕСТВЕННО НЕПРЯМОГО ДЕЙСТВИЯ
ОТНОСИТЕЛЬНО НИЗКОЕ КАЧЕСТВО МЕДИЦИНСКОГО ОБСЛУЖИВАНИЯ
НЕДОСТАТОЧНЫЙ УРОВЕНЬ ПРОФИЛАКТИКИ ЗАБОЛЕВАНИЙ
НАЛИЧИЕ ДИСПРОПОРЦИЙ В ОКАЗАНИИ МЕДИЦИНСКОЙ ПОМОЩИ ГОРОДСКОМУ И СЕЛЬСКОМУ НАСЕЛЕНИЮ
НИЗКАЯ ДОСТУПНОСТЬ НАСЕЛЕНИЮ ВЫСОКОТЕХНОЛОГИЧНОЙ МЕДИЦИНСКОЙ ПОМОЩИ
НЕУКОМПЛЕКТОВАННОСТЬ КАДРАМИ ПЕРВИЧНОГО ЗВЕНА ЗДРАВООХРАНЕНИЯ
НИЗКАЯ ЭКОНОМИЧЕСКАЯ ЭФФЕКТИВНОСТЬ ИСПОЛЬЗОВАНИЯ РЕСУРСОВ
СЛАБАЯ МАТЕРИАЛЬНО-ТЕХНИЧЕСКАЯ БАЗА УЧРЕЖДЕНИЙ ЗДРАВООХРАНЕНИЯ
ШИРОКОЕ РАЗВИТИЕ СТАЦИОНАРНЫХ СЛУЖБ
ПРЕОБЛАДАНИЕ ВРАЧЕЙ-СПЕЦИАЛИСТОВ, НЕХВАТКА СЕСТРИНСКОГО ПЕРСОНАЛА


СИСТЕМНОЕ РЕФОРМИРОВАНИЕ ОТРАСЛИ
ДОЛЖНО ВКЛЮЧАТЬ
ФИНАНСОВО-ЭКОНОМИЧЕСКУЮ РЕФОРМУ, ВКЛЮЧАЯ РЕСТРУКТУРИЗАЦИЮ ЗДРАВООХРАНЕНИЯ
ПОВЫШЕНИЕ КАЧЕСТВА УПРАВЛЕНИЯ ОТРАСЛЬЮ НА ОСНОВЕ НАУЧНО ОБОСНОВАННЫХ ТЕХНОЛОГИЯХ СОВРЕМЕННОГО МЕНЕДЖМЕНТА ЗДРАВООХРАНЕНИЯ
РАЗВИТИЕ МЕДИЦИНСКОЙ ПРАКТИКИ, ОСНОВАННОЙ НА ПРИНЦИПАХ ДОКАЗАТЕЛЬНОЙ МЕДИЦИНЫ И РЕЗУЛЬТАТАХ КЛИНИКО-ЭКОНОМИЧЕСКОГО АНАЛИЗА

ПРЕИМУЩЕСТВА СОВЕТСКОЙ МОДЕЛИ ЗДРАВООХРАНЕНИЯ

- ПОЛНЫЙ ОХВАТ ВСЕГО НАСЕЛЕНИЯ МЕДИЦИНСКОЙ ПОМОЩЬЮ, ПРЕДОСТАВЛЯЕМОЙ ЗА СЧЕТ БЮДЖЕТНЫХ СРЕДСТВ
- ЧЕТКАЯ ИЕРАРХИЧЕСКАЯ ОРГАНИЗАЦИОННАЯ СТРУКТУРА ОРГАНОВ УПРАВЛЕНИЯ ЗДРАВООХРАНЕНИЕМ И СЕТИ УЧРЕЖДЕНИЙ ЗДРАВООХРАНЕНИЯ
- ВОЗМОЖНОСТЬ ОРГАНИЗОВЫВАТЬ И ВЫПОЛНЯТЬ КРУПНОМАСШТАБНЫЕ ОБЩЕГОСУДАРСТВЕННЫЕ МЕРОПРИЯТИЯ, ПРОГРАММЫ В СФЕРЕ ОХРАНЫ ЗДОРОВЬЯ НАСЕЛЕНИЯ
- ОТНОСИТЕЛЬНО НИЗКИЕ АДМИНИСТРАТИВНЫЕ РАСХОДЫ В ВИДУ ИСПОЛЬЗОВАНИЯ ПРЯМОГО БЮДЖЕТНОГО ФИНАНСИРОВАНИЯ И ОТСУТСТВИЯ РАСХОДОВ НА СБОР И ТРАНСЛЯЦИЮ ФИНАНСОВЫХ СРЕДСТВ С ИСПОЛЬЗОВАНИЕМ СЕТИ СТРАХОВЫХ МЕДИЦИНСКИХ ОРГАНИЗАЦИЙ
- ЦЕНТРАЛИЗАЦИЯ ФИНАНСОВЫХ, КАДРОВЫХ, МАТЕРИАЛЬНО-ТЕХНИЧЕСКИХ РЕСУРСОВ ПРИ ОКАЗАНИИ АМБУЛАТОРНОЙ ПОМОЩИ В ПОЛИКЛИНИКАХ

НЕДОСТАТКИ СОВЕТСКОЙ МОДЕЛИ ЗДРАВООХРАНЕНИЯ

- ОГРАНИЧЕНИЕ ВОЗМОЖНОСТИ ИСПОЛЬЗОВАНИЯ ЭКОНОМИЧЕСКИХ МЕТОДОВ УПРАВЛЕНИЯ
- ВЫДЕЛЕНИЕ ФИНАНСОВЫХ СРЕДСТВ ДЛЯ СОДЕРЖАНИЯ ОРГАНИЗАЦИЙ ЗДРАВООХРАНЕНИЯ, ИСХОДЯ ИЗ ИХ МОЩНОСТИ, А НЕ ОПЛАТЫ ОКАЗАННЫХ ИЛИ ПЛАНИРУЕМЫХ ОБЪЕМОВ МЕДИЦИНСКОЙ ПОМОЩИ ПО УСТАНОВЛЕННЫМ ТАРИФАМ

В КОНЕЧНОМ ИТОГЕ ЭТО ОКАЗЫВАЕТ НЕПОСРЕДСТВЕННОЕ ВЛИЯНИЕ НА РЕШЕНИЕ КОМПЛЕКСА ПРОБЛЕМ ИНТЕНСИФИКАЦИИ И ПОВЫШЕНИЯ КАЧЕСТВА ЛЕЧЕБНО-ДИАГНОСТИЧЕСКОГО ПРОЦЕССА, МОТИВАЦИИ ТРУДА, РАЦИОНАЛЬНОГО ИСПОЛЬЗОВАНИЯ И РАСПРЕДЕЛЕНИЯ РЕСУРСОВ

ОСОБЕННОСТИ МОДЕЛЕЙ ЗДРАВООХРАНЕНИЯ ЭКОНОМИЧЕСКИ РАЗВИТЫХ СТРАН

- СОЧЕТАНИЕ РАЗЛИЧНЫХ ФОРМ СОБСТВЕННОСТИ
- ЭКОНОМИЧЕСКАЯ САМОСТОЯТЕЛЬНОСТЬ ПОСТАВЩИКОВ МЕДИЦИНСКИХ УСЛУГ В ИСПОЛЬЗОВАНИИ ЗАРАБАТЫВАЕМЫХ ФИНАНСОВЫХ СРЕДСТВ
- ОТСУТСТВИЕ ФИНАНСООБРАЗУЮЩИХ ФУНКЦИЙ, ПРИДАВАЕМЫХ УСЛОВНЫМ ЕДИНИЦАМ – БОЛЬНИЧНЫМ КОЙКАМ
- ОТСУТСТВИЕ ШТАТНЫХ НОРМАТИВОВ
- ПРЕИМУЩЕСТВЕННАЯ ОРИЕНТАЦИЯ БОЛЬНИЦ НА КРАТКОСРОЧНОЕ ИНТЕНСИВНОЕ ЛЕЧЕНИЕ ОСТРЫХ ЗАБОЛЕВАНИЙ
- ВЫСОКИЙ УРОВЕНЬ ОБЕСПЕЧЕННОСТИ БОЛЬНИЦ МЕДИЦИНСКИМ ПЕРСОНАЛОМ
- ИСПОЛЬЗОВАНИЕ МЕДИЦИНСКОГО ПАТРОНАЖА НА ДОМУ
- РАЗНООБРАЗИЕ РЕЖИМОВ ПРЕБЫВАНИЯ БОЛЬНОГО В СТАЦИОНАРЕ
- РАВНОМЕРНОЕ ИСПОЛЬЗОВАНИЕ БОЛЬНИЧНЫХ РЕСУРСОВ
- НАЛИЧИЕ В БОЛЬНИЦАХ ОТДЕЛЕНИЙ СКОРОЙ МЕДИЦИНСКОЙ ПОМОЩИ С ФУНКЦИЯМИ ДОСТАВКИ ПАЦИЕНТОВ В БОЛЬНИЦУ, А ТАКЖЕ ПОЛИКЛИНИЧЕСКИХ ОТДЕЛЕНИЙ
- ИНТЕГРАЦИЯ ФУНКЦИЙ МЕДИЦИНСКОГО И СОЦИАЛЬНОГО ОБЕСПЕЧЕНИЯ И РОСТ ОБЪЕМОВ МЕДИКО-СОЦИАЛЬНОЙ ПОМОЩИ
- ПРИБЛИЖЕНИЕ ФУНКЦИЙ СЕСТРИНСКОГО ПЕРСОНАЛА К ВРАЧЕБНЫМ
- РЕАЛИЗАЦИЯ ПРИНЦИПОВ ВРАЧЕБНОГО САМОУПРАВЛЕНИЯ И ВЫСОКАЯ РОЛЬ ВРАЧЕБНЫХ АССОЦИАЦИЙ
- ФОРМИРОВАНИЕ И ФУНКЦИОНИРОВАНИЕ ОБЩЕСТВЕННЫХ ОРГАНИЗАЦИЙ

Совершенствование (реформирование) систем здравоохранения

РОССИЯ

ПОСТРОЕНИЕ БЮДЖЕТНО-СТРАХОВОЙ МОДЕЛИ

КАЗАХСТАН

ПОПЫТКА ВВЕДЕНИЯ ОБЯЗАТЕЛЬНОГО МЕДИЦИНСКОГО СТРАХОВАНИЯ

КЫРГИЗСТАН

МОЛДОВА

ПЕРЕХОД К ОБЯЗАТЕЛЬНОМУ МЕДИЦИНСКОМУ СТРАХОВАНИЮ

ПРОЦЕСС СТРУКТУРНЫХ ПРЕОБРАЗОВАНИЙ В СИСТЕМЕ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ

КОНЦЕПЦИЯ РАЗВИТИЯ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ НА 1998-2002 ГГ.

КОНЦЕПЦИЯ РАЗВИТИЯ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ НА 2003-2007 ГГ.

В КОНЦЕ 80-Х – В НАЧАЛЕ 90-Х ГОДОВ В БЕЛАРУСИ АКТИВНО БЫЛ ПОДДЕРЖАН ПРОВОДИВШИЙСЯ В ТРЕХ РЕГИОНАХ РОССИИ ЭКСПЕРИМЕНТ ПО ВНЕДРЕНИЮ ТАК НАЗЫВАЕМОГО "НОВОГО ХОЗЯЙСТВЕННОГО МЕХАНИЗМА".

В ДВУХ РАЙОНАХ РЕСПУБЛИКИ (СВИСЛОЧСКИЙ РАЙОН ГРОДНЕНСКОЙ ОБЛАСТИ И УЗДЕНСКИЙ МИНСКОЙ ОБЛАСТИ) БЫЛА СДЕЛАНА ПОПЫТКА ПЕРЕХОДА НА ВНУТРИСИСТЕМНЫЕ АРЕНДНЫЕ ОТНОШЕНИЯ С ЗАКЛЮЧЕНИЕМ СООТВЕТСТВУЮЩИХ ДОГОВОРОВ С РАЙОННЫМИ ИСПОЛНИТЕЛЬНЫМИ КОМИТЕТАМИ

«ПУСКОВОЙ МЕХАНИЗМ» ПРОЦЕССА РЕФОРМИРОВАНИЯ - ПРОВЕДЕНИЕ В 2001-2002 ГОДАХ ЭКСПЕРИМЕНТА ПО СОВЕРШЕНСТВОВАНИЮ МЕХАНИЗМА ХОЗЯЙСТВОВАНИЯ В ОРГАНИЗАЦИЯХ ЗДРАВООХРАНЕНИЯ ВИТЕБСКОЙ ОБЛАСТИ

В ХОДЕ ЭКСПЕРИМЕНТА:
- ОТРАБОТАНА МЕТОДИКА РАСПРЕДЕЛЕНИЯ ФИНАНСОВЫХ СРЕДСТВ ПО НОРМАТИВАМ БЮДЖЕТНОЙ ОБЕСПЕЧЕННОСТИ РАСХОДОВ НА ЗДРАВООХРАНЕНИЕ В РАСЧЕТЕ НА ОДНОГО ЖИТЕЛЯ;
- БАЗИСНАЯ МЕТОДИКА РАЗРАБОТКИ ТЕРРИТОРИАЛЬНЫХ ПРОГРАММ ГОСУДАРСТВЕННЫХ ГАРАНТИЙ ОКАЗАНИЯ БЕСПЛАТНОЙ МЕДИЦИНСКОЙ ПОМОЩИ

Концепция развития здравоохранения Республики Беларусь на 1998-2002 гг.

- ДОСТИГНУТА СТАБИЛЬНОСТЬ В РАБОТЕ ОТРАСЛИ
- НАЧАТО ВНЕДРЕНИЕ НОВЫХ ЭКОНОМИЧЕСКИХ ФОРМ УПРАВЛЕНИЯ
- СОЗДАНЫ УСЛОВИЯ ДЛЯ РАЗРАБОТКИ И ВНЕДРЕНИЯ НОВОЙ МЕДИКО-ЭКОНОМИЧЕСКОЙ МОДЕЛИ ЗДРАВООХРАНЕНИЯ

ПО РЯДУ ПОКАЗАТЕЛЕЙ ДЕЯТЕЛЬНОСТИ СИСТЕМЫ ЗДРАВООХРАНЕНИЯ, СОСТОЯНИЯ ЗДОРОВЬЯ НАСЕЛЕНИЯ, НЕПОСРЕДСТВЕННО РЕГУЛИРУЕМЫХ ЗДРАВООХРАНЕНИЕМ, РЕСПУБЛИКА БЕЛАРУСЬ ЗАНИМАЛА ОДНО ИЗ ВЕДУЩИХ МЕСТ СРЕДИ СТРАН СНГ

Концепция развития здравоохранения Республики Беларусь на 1998-2002 гг.

- ВНЕДРЕНИЕ СИСТЕМЫ ФИНАНСИРОВАНИЯ СОГЛАСНО НОРМАТИВАМ БЮДЖЕТНОЙ ОБЕСПЕЧЕННОСТИ РАСХОДОВ НА ЗДРАВООХРАНЕНИЕ В РАСЧЕТЕ НА ОДНОГО ЖИТЕЛЯ
- ВНЕДРЕНИЕ ПРИНЦИПОВ ПРОГРАММНО-ЦЕЛЕВОГО ПЛАНИРОВАНИЯ
- ПРОВЕДЕНИЕ НАЧАЛЬНОГО ЭТАПА РЕСТРУКТУРИЗАЦИИ ЗДРАВООХРАНЕНИЯ
- РАБОТА В ОБЛАСТИ СТАНДАРТИЗАЦИИ МЕДИЦИНСКИХ ТЕХНОЛОГИЙ
- ФОРМИРОВАНИЕ СИСТЕМЫ ГОСУДАРСТВЕННЫХ СОЦИАЛЬНЫХ СТАНДАРТОВ В ОБЛАСТИ ЗДРАВООХРАНЕНИЯ

Концепция развития здравоохранения Республики Беларусь на 2003-2007 годы

ОПРЕДЕЛЕНЫ ОСНОВЫ НОВОЙ МЕДИКО-ЭКОНОМИЧЕСКОЙ МОДЕЛИ ЗДРАВООХРАНЕНИЯ БЕЛАРУСИ:

- ПЕРЕХОД НА ПОДУШЕВУЮ СИСТЕМУ ФИНАНСИРОВАНИЯ
- КОНКРЕТИЗАЦИЯ СОЦИАЛЬНЫХ ОБЯЗАТЕЛЬСТВ ГОСУДАРСТВА В ОБЛАСТИ ЗДРАВООХРАНЕНИЯ
- РЕСТРУКТУРИЗАЦИЯ ЗДРАВООХРАНЕНИЯ С ПЕРЕРАСПРЕДЕЛЕНИЕМ РЕСУРСОВ НА БОЛЕЕ ЭФФЕКТИВНЫЕ НАПРАВЛЕНИЯ ДЕЯТЕЛЬНОСТИ
- СОВЕРШЕНСТВОВАНИЕ УПРАВЛЕНИЯ КАЧЕСТВОМ МЕДИЦИНСКОЙ ПОМОЩИ

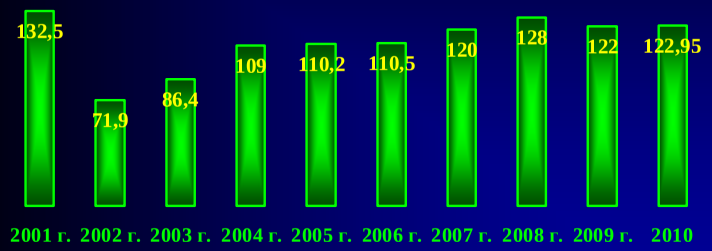
ОСНОВНЫЕ ПРЕОБРАЗОВАНИЯ В ЗДРАВООХРАНЕНИИ РЕСПУБЛИКИ БЕЛАРУСЬ

1. ИЗМЕНЕН ПРИНЦИП ФИНАНСИРОВАНИЯ ЗДРАВООХРАНЕНИЯ
2. КОНКРЕТИЗИРОВАНЫ СОЦИАЛЬНЫЕ ОБЯЗАТЕЛЬСТВА ГОСУДАРСТВА В ОБЛАСТИ ЗДРАВООХРАНЕНИЯ
3. ОПТИМИЗИРОВАНА СТРУКТУРА УПРАВЛЕНИЯ ОРГАНИЗАЦИЯМИ ЗДРАВООХРАНЕНИЯ С ЦЕЛЬЮ ЛИКВИДАЦИИ ДУБЛИРОВАНИЯ ФУНКЦИЙ УПРАВЛЕНИЯ
4. ВНЕДРЕНО ПРОГРАММНО-ЦЕЛЕВОЕ ПЛАНИРОВАНИЕ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ
5. ПРОДОЛЖЕН ПРОЦЕСС РЕСТРУКТУРИЗАЦИИ ОТРАСЛИ
6. УСОВЕРШЕНСТВОВАНА СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ МЕДИЦИНСКОЙ ПОМОЩИ
7. В РАМКАХ ГОСУДАРСТВЕННЫХ ПРОГРАММ УЛУЧШЕНО МАТЕРИАЛЬНО-ТЕХНИЧЕСКОЕ ОСНАЩЕНИЕ ОРГАНИЗАЦИЙ ЗДРАВООХРАНЕНИЯ, В ТОМ ЧИСЛЕ СЕЛЬСКИХ
8. ОПТИМИЗИРОВАНО КАДРОВОЕ ОБЕСПЕЧЕНИЕ ОТРАСЛИ
9. НОРМАТИВНАЯ ПРАВОВАЯ БАЗА ЗДРАВООХРАНЕНИЯ ПРИВЕДЕНА В СООТВЕТСТВИЕ С ТРЕБОВАНИЯМИ НОВОГО ЭТАПА ЕГО РАЗВИТИЯ
10. УЛУЧШЕНА ДОСТУПНОСТЬ ДЛЯ НАСЕЛЕНИЯ ЛЕКАРСТВЕННЫХ СРЕДСТВ
11. ПРИНЯТЫ МЕРЫ ПО СОВЕРШЕНСТВОВАНИЮ СТАТИСТИЧЕСКОГО УЧЕТА И ИНФОРМАТИЗАЦИИ ОТРАСЛИ

СОВЕРШЕНСТВОВАНИЕ ЭКОНОМИЧЕСКИХ ОТНОШЕНИЙ

- ИЗМЕНЕНИЕ ЭКОНОМИЧЕСКОЙ САМОСТОЯТЕЛЬНОСТИ В ИСПОЛЬЗОВАНИИ ЗАРАБАТЫВАЕМЫХ ФИНАНСОВЫХ СРЕДСТВ
- ПЕРЕХОД К ОПЛАТЕ ПО УСТАНОВЛЕННЫМ ТАРИФАМ КОНКРЕТНЫХ, ЗАКАЗАННЫХ, СОГЛАСОВАННЫХ ОБЪЕМОВ СТАЦИОНАРНОЙ И СКОРОЙ МЕДИЦИНСКОЙ ПОМОЩИ
- ФИНАНСИРОВАНИЕ ГОСУДАРСТВЕННЫХ АМБУЛАТОРНО-ПОЛИКЛИНИЧЕСКИХ ОРГАНИЗАЦИЙ ПО НОРМАТИВАМ НА ОДНОГО ПРИКРЕПЛЕННОГО ЖИТЕЛЯ
- РОСТ ПЕРЕМЕННОЙ (Т.Е. ПРЕМИАЛЬНОЙ) ЧАСТИ ЗАРАБОТНОЙ ПЛАТЫ В СРАВНЕНИИ С ПОСТОЯННОЙ (ДОЛЖНОСТНЫМ ОКЛАДОМ)

Темпы роста платных медицинских услуг (%)



Развитие платной медицины

СОЗДАНИЕ БЛАГОПРИЯТНЫХ УСЛОВИЙ ДЛЯ РАЗВИТИЯ ПЛАТНЫХ МЕДИЦИНСКИХ УСЛУГ В ГОСУДАРСТВЕННЫХ ОРГАНИЗАЦИЯХ ЗДРАВООХРАНЕНИЯ И В ГОСУДАРСТВЕННЫХ УНИТАРНЫХ ПРЕДПРИЯТИЯХ

ДЛЯ РОСТА ЭКСПОРТА МЕДИЦИНСКИХ УСЛУГ ТРЕБУЕТСЯ:

- ПРОДОЛЖЕНИЕ ПОЛИТИКИ МОДЕРНИЗАЦИИ СИСТЕМЫ ЗДРАВООХРАНЕНИЯ С ОБЕСПЕЧЕНИЕМ ЗАКУПОК СОВРЕМЕННОГО ОБОРУДОВАНИЯ
- ХОРОШО НАЛАЖЕННЫЙ МАРКЕТИНГ С УГЛУБЛЕННЫМ ИЗУЧЕНИЕМ РЫНКА УСЛУГ, ОПТИМАЛЬНЫМ ЦЕНООБРАЗОВАНИЕ М И РЕКЛАМОЙ

Развитие и упорядочение нормативной правовой базы здравоохранения

- ФОРМИРОВАНИЕ КОДЕКСА РЕСПУБЛИКИ БЕЛАРУСЬ ОБ ОХРАНЕ ЗДОРОВЬЯ ГРАЖДАН ИЛИ КОДЕКСА ЗАКОНОВ ОБ ОХРАНЕ ЗДОРОВЬЯ ГРАЖДАН РЕСПУБЛИКИ БЕЛАРУСЬ
- ДАЛЬНЕЙШЕЕ ФОРМИРОВАНИЕ ЕДИНОЙ ОТРАСЛЕВОЙ ЭЛЕКТРОННОЙ БАЗЫ ДАННЫХ ПО НОРМАТИВНЫМ ПРАВОВЫМ АКТАМ И ДРУГИМ ОРГАНИЗАЦИОННО-МЕТОДИЧЕСКИМ ДОКУМЕНТАМ
- УСИЛЕНИЕ ПРЯМОЙ РЕГУЛИРУЮЩЕЙ РОЛИ ЗАКОНОВ В СИСТЕМЕ ЗДРАВООХРАНЕНИЯ И СНИЖЕНИЕ КОЛИЧЕСТВА «ОТСЫЛОЧНЫХ» ПРАВОВЫХ НОРМ
- СТАНОВЛЕНИЕ МЕДИЦИНСКОГО ПРАВА КАК САМОСТОЯТЕЛЬНОГО НАПРАВЛЕНИЯ ПРАВОВЕДЕНИЯ И ИЗУЧЕНИЕ ЕГО В МЕДИЦИНСКИХ УНИВЕРСИТЕТАХ

ПЛАНИРОВАНИЕ В ЗДРАВООХРАНЕНИИ — ЭТО ОБОСНОВАНИЕ И РАЗРАБОТКА ОПРЕДЕЛЕННОГО СООТНОШЕНИЯ ПОТРЕБНОСТЕЙ НАСЕЛЕНИЯ В УСЛУГАХ СИСТЕМЫ ЗДРАВООХРАНЕНИЯ С ПРАКТИЧЕСКИМИ ВОЗМОЖНОСТЯМИ ИХ УДОВЛЕТВОРЕНИЯ

Основные принципы планирования здравоохранения

- НАУЧНАЯ ОБОСНОВАННОСТЬ И ЭКОНОМИЧЕСКАЯ ЭФФЕКТИВНОСТЬ РАЗРАБАТЫВАЕМЫХ ПЛАНОВ
- ОБЯЗАТЕЛЬНОЕ ВЫДЕЛЕНИЕ ПРИОРИТЕТНЫХ ЗАДАЧ, А ТАКЖЕ ПОКАЗАТЕЛЕЙ, КОТОРЫЕ НАИБОЛЕЕ ТОЧНО ХАРАКТЕРИЗУЮТ СТЕПЕНЬ ДОСТИЖЕНИЯ ЦЕЛЕЙ
- СОЧЕТАНИЕ ТЕКУЩЕГО И ПЕРСПЕКТИВНОГО, ОТРАСЛЕВОГО И ТЕРРИТОРИАЛЬНОГО ПЛАНИРОВАНИЯ

Основные элементы планирования в системе здравоохранения на современном этапе

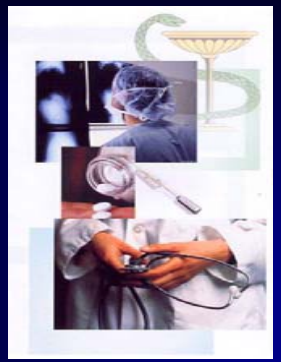
- ГОСУДАРСТВЕННЫЕ И ОТРАСЛЕВЫЕ ПРОГРАММЫ В СФЕРЕ ОХРАНЫ ЗДОРОВЬЯ
- СИСТЕМА ГОСУДАРСТВЕННЫХ СОЦИАЛЬНЫХ СТАНДАРТОВ
- ТЕРРИТОРИАЛЬНЫЕ ПРОГРАММЫ ГОСУДАРСТВЕННЫХ ГАРАНТИЙ ОКАЗАНИЯ ГРАЖДАНАМ БЕСПЛАТНОЙ МЕДИЦИНСКОЙ ПОМОЩИ

Программно-целевое планирование в современных условиях – это основной вид стратегического планирования

- КООРДИНАЦИЯ РАБОТЫ РАЗЛИЧНЫХ ОРГАНОВ ГОСУДАРСТВЕННОГО УПРАВЛЕНИЯ
- ВОЗМОЖНОСТЬ ДОСТИЖЕНИЯ КОНКРЕТНЫХ РЕЗУЛЬТАТОВ В УСТАНАВЛИВАЕМЫЕ СРОКИ
- ЦЕЛЕВОЕ РАСПРЕДЕЛЕНИЕ БЮДЖЕТНЫХ СРЕДСТВ
- ОБЕСПЕЧЕНИЕ МОНИТОРИНГА ДОСТИЖЕНИЯ ЦЕЛЕЙ

ГОСУДАРСТВЕННЫЕ ПРОГРАММЫ

- ПРЕЗИДЕНТСКАЯ ПРОГРАММА "ДЕТИ БЕЛАРУСИ" НА 2006 – 2010 гг.
- РАЗВИТИЯ ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ НА 2006-2010 гг.
- ПРОГРАММА ПРОФИЛАКТИКИ ВИЧ-ИНФЕКЦИИ
- ПО ПРЕДУПРЕЖДЕНИЮ ИНВАЛИДНОСТИ И РЕАБИЛИТАЦИИ ИНВАЛИДОВ
- ОБЕСПЕЧЕНИЯ САНИТАРНО-ЭПИДЕМИЧЕСКОГО БЛАГОПОЛУЧИЯ НАСЕЛЕНИЯ РЕСПУБЛИКИ БЕЛАРУСЬ НА 2007 – 2010 гг.



- ПО ПРЕОДОЛЕНИЮ ПОСЛЕДСТВИЙ КАТАСТРОФЫ НА ЧЕРНОБЫЛЬСКОЙ АЭС НА 2001-2005 ГОДЫ И НА ПЕРИОД ДО 2010 ГОДА
- НАЦИОНАЛЬНАЯ ПРОГРАММА ДЕМОГРАФИЧЕСКОЙ БЕЗОПАСНОСТИ РЕСПУБЛИКИ БЕЛАРУСЬ НА 2007 – 2010 гг.
- ВОЗРОЖДЕНИЯ И РАЗВИТИЯ СЕЛА НА 2005-2010 гг.
- НАЦИОНАЛЬНЫХ ДЕЙСТВИЙ ПО ПРЕДУПРЕЖДЕНИЮ И ПРЕОДОЛЕНИЮ ПЬЯНСТВА И АЛКОГОЛИЗМА НА 2006–2010 гг.
- «ТУБЕРКУЛЕЗ»
- ИННОВАЦИОННОГО РАЗВИТИЯ РЕСПУБЛИКИ БЕЛАРУСЬ НА 2007-2010 гг.

Система государственных социальных стандартов в области здравоохранения

- ПРИНЦИПИАЛЬНО НОВОЕ НАПРАВЛЕНИЕ ДЕЯТЕЛЬНОСТИ
- ПРАКТИЧЕСКИ НЕ ИМЕЕТ АНАЛОГОВ В ЗАРУБЕЖНЫХ СТРАНАХ
- ВАЖНЕЙШИЙ МЕХАНИЗМ КОНКРЕТИЗАЦИИ УРОВНЯ ГОСУДАРСТВЕННЫХ ГАРАНТИЙ В ОБЛАСТИ ЗДРАВООХРАНЕНИЯ

Предложения по уточнению содержания и расчета государственных социальных стандартов в области здравоохранения

- норматив бюджетной обеспеченности расходов на здравоохранение на одного жителя на очередной год определять по республике в целом; средний норматив по бюджетам областей и г. Минска; норматив для каждой области и г. Минска;
- оценку выполнения данного норматива осуществлять по итогам работы за финансовый год, а не ежеквартально;
- расчет данного норматива производить с учетом капитальных вложений в здравоохранение.
- норматив обеспеченности врачами первичного звена рассчитывать на занятые должности с учетом врачей ведомственного здравоохранения и коэффициента совместительства без разбивки по врачебным должностям.
- Расчет коек проводить с учетом коек отделений анестезиологии-реанимации с палатами реанимации и интенсивной терапии, а также коек ведомственных организаций здравоохранения;
- расчет коек на районном уровне проводить с учетом использования коечного фонда областных и республиканских организаций здравоохранения.
- Уточнить содержание норматива санитарно-технического обеспечения организаций здравоохранения, заменив слова «приточно-вытяжной вентиляции» на «вентиляции с естественным побуждением».

Приорететное развитие амбулаторно-поликлинической помощи

- финансирование объемов амбулаторно-поликлинической помощи увеличено до 40%
- активизирована работа по внедрению стационарзамещающих технологий
- расширен объем амбулаторной хирургической помощи диагностических и консультативных специализированных центров
- на конец 2010 г. введено 732 должности помощника врача против 62 – в 2009 г.
- подготовлено 564 врача общей практики

Основная задача врачей первичного звена, кардиологов и других специалистов – работа по профилактике факторов риска, раннему выявлению основных социально значимых заболеваний, более интенсивная и результативная работа в группах часто и длительно болеющих лиц трудоспособного возраста.

Стратегические приоритеты государственной политики в области здравоохранения

- СОВЕРШЕНСТВОВАНИЕ ЭКОНОМИЧЕСКИХ МЕХАНИЗМОВ В ЗДРАВООХРАНЕНИИ
- ОХРАНА ЗДОРОВЬЯ МАТЕРИ И РЕБЕНКА
- УСИЛЕНИЕ ПРОФИЛАКТИЧЕСКОЙ НАПРАВЛЕННОСТИ ЗДРАВООХРАНЕНИЯ
- СОВЕРШЕНСТВОВАНИЕ СИСТЕМЫ ПОДГОТОВКИ И ПЕРЕПОДГОТОВКИ МЕДИЦИНСКИХ КАДРОВ
- ОБЕСПЕЧЕНИЕ ПРАВОВОЙ И СОЦИАЛЬНОЙ ЗАЩИТЫ РАБОТНИКА ОТРАСЛИ
- КОНЦЕНТРАЦИЯ ИНТЕЛЛЕКТУАЛЬНЫХ, МАТЕРИАЛЬНО-ТЕХНИЧЕСКИХ И ФИНАНСОВЫХ РЕСУРСОВ МЕДИЦИНСКОЙ НАУКИ НА РЕШЕНИИ ПЕРВООЧЕРЕДНЫХ ЗАДАЧ ПРАКТИЧЕСКОГО ЗДРАВООХРАНЕНИЯ
- СОВЕРШЕНСТВОВАНИЕ ИНФОРМАТИЗАЦИИ ЗДРАВООХРАНЕНИЯ И СОЗДАНИЕ ЕДИНОЙ СИСТЕМЫ МОНИТОРИНГА ЗДОРОВЬЯ НАСЕЛЕНИЯ
- ОСУЩЕСТВЛЕНИЕ МЕЖДУНАРОДНОГО СОТРУДНИЧЕСТВА В СООТВЕТСТВИИ С ОСНОВНЫМИ ПРИОРИТЕТАМИ И НАПРАВЛЕНИЯМИ РАЗВИТИЯ МЕДИЦИНСКОЙ ПОМОЩИ В РЕСПУБЛИКЕ БЕЛАРУСЬ
- ОБЕСПЕЧЕНИЕ ЭФФЕКТИВНЫМИ, БЕЗОПАСНЫМИ И КАЧЕСТВЕННЫМИ ЛЕКАРСТВЕННЫМИ СРЕДСТВАМИ
- РАЗВИТИЕ САНИТАРНО-ЭПИДЕМИОЛОГИЧЕСКОЙ СЛУЖБЫ
- КООРДИНАЦИЯ ДЕЯТЕЛЬНОСТИ ОРГАНОВ ВЛАСТИ И УПРАВЛЕНИЯ РАЗЛИЧНЫХ УРОВНЕЙ, ДРУГИХ МИНИСТЕРСТВ И ВЕДОМСТВ ПО РЕШЕНИЮ ВОПРОСОВ ЗДРАВООХРАНЕНИЯ

Информатизация отрасли

- 54,2% **амбулаторно-поликлинических организаций имеют локальные вычислительные сети**
- в 57,3% из них внедрены автоматизированные рабочие места «Регистратура»
- в 42,2% - АРМ «Диспансеризация»
- в 66,2% - «Статистика»
- 73,1% АПУ и их филиалов имели подключение к Интернет и электронной почте

В 439 врачебных амбулаториях и амбулаториях врача общей практики внедрена АИС «Врач общей практики», что составляет около 70% от их общего количества.

Телемедицинская система охватывает:
11 организаций здравоохранения районного уровня (ЦРБ)
9 – областного уровня
10 – республиканского уровня (РНПЦ)

Основные задачи информатизации

- обеспечение электронного документооборота, в том числе внедрение электронных медицинских карт ведения больных в амбулаторных и стационарных условиях, пожизненной электронной медицинской карты пациента
- внедрение автоматизированных информационных систем по мониторингу здоровья населения, диспансеризации населения, планированию и учету кадров, стандартам медицинских технологий
- выделение базовых организаций здравоохранения, выполняющих функции учебно-методических центров по внедрению компьютерных информационных технологий
- организация подготовки специалистов в области медицинской информатики
- развитие телекоммуникационной сети и средств телемедицины
- широкое использование в образовательных и информационных целях интернет-ресурсов
- подготовка электронных учебников

Основные задачи системы здравоохранения

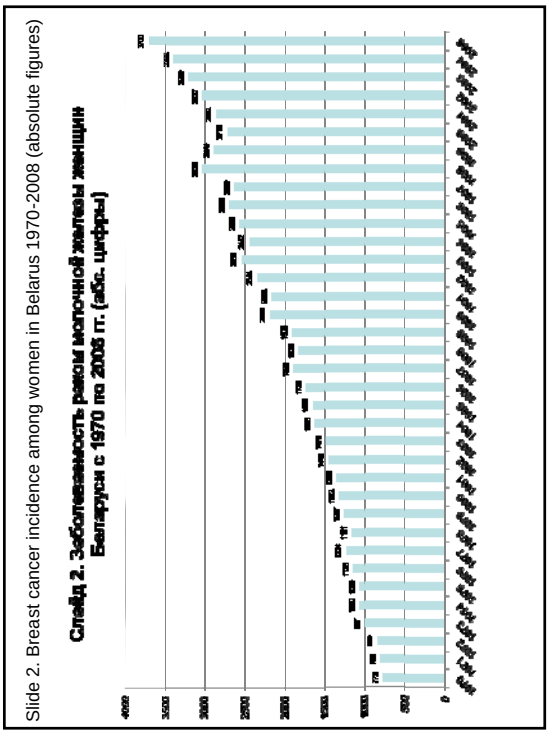
- повышение у граждан ответственности за свое здоровье, формирование мотивации к здоровому образу жизни, искоренению вредных привычек
- организация профилактических мероприятий по раннему выявлению факторов риска социально значимых заболеваний, улучшение качества их диагностики, лечения и реабилитации пациентов
- реализация комплекса мер по улучшению репродуктивного здоровья населения, охране здоровья матери и ребенка
- обеспечение граждан доступной и качественной медицинской помощью на всех уровнях ее оказания с использованием новых современных методов диагностики и лечения
- снижение смертности как результат реализации мероприятий, направленных на укрепление здоровья населения
- улучшение качества жизни людей с хроническими заболеваниями и инвалидов путем создания условий для их реабилитации и социализации
- развитие медицинской науки, расширение международного сотрудничества, инновационной деятельности и реализации комплекса мер, направленных на повышение конкурентоспособности и инвестиционной привлекательности

The role of breast self-examination and clinical examination in early detection of breast cancer

Prof. Putyrski L.A.

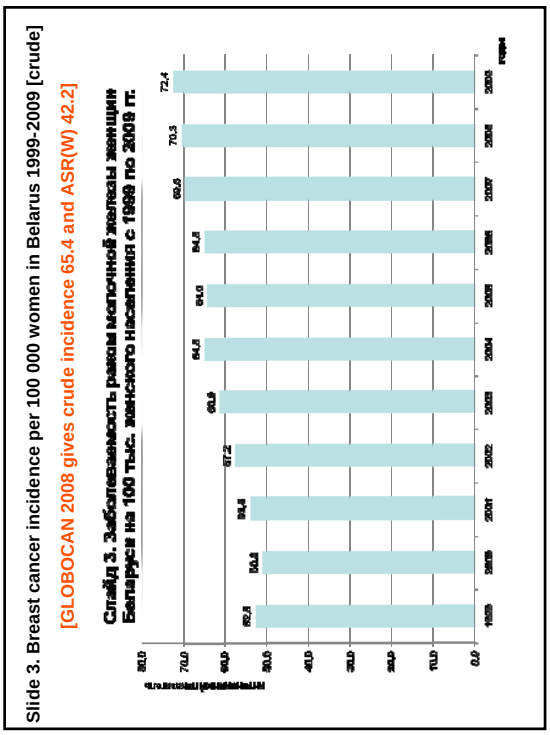
N.N. Aleksandrov research centre and clinic for oncology and medical radiology

Slide 2. Breast cancer incidence among women in Belarus 1970-2008 (absolute figures)



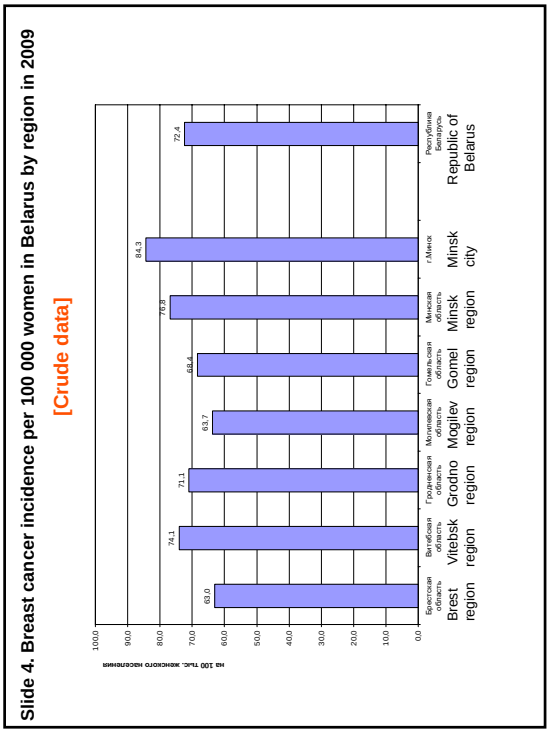
Slide 3. Breast cancer incidence per 100 000 women in Belarus 1999-2009 [crude]

[GLOBOCAN 2008 gives crude incidence 65.4 and ASR(W) 42.2]



Slide 4. Breast cancer incidence per 100 000 women in Belarus by region in 2009

[Crude data]



The goal of examination – to decrease advanced breast cancers among the female population in the Republic of Belarus using an integrated method of early diagnosis (self examination and clinical examination by specialists of therapeutic and prophylactic organizations).

Tasks:

1. To improve the integrated method for early detection of breast cancer, including self-examination and clinical examination by specialists of therapeutic and prophylactic organizations, to prove its effectiveness in early detection of the disease.

2. Develop algorithms and tactics of examination of healthy women as well as patients with identified pathological changes in the mammary glands.

Tasks:

3. Evaluate the effectiveness of the integrated method of early detection of breast cancer, including self-examination and clinical examination by specialists of therapeutic and prophylactic organizations to reduce the one-year mortality and primary disability, and to increase the proportion of women survivors of 5 or more years from the date of diagnosis.

Tasks:

4. Evaluate the economic effect of reducing advanced disease in women of the Republic of Belarus that is expressed in the reduced cost of treating patients with primary breast cancer.

Scientific novelty:

1. For the first time in the Republic of Belarus, the importance of development and introduction into clinical practice of a complex method of early diagnosis of breast cancer through self-examination and clinical examination has been assessed, which reduced advanced breast cancer in Belarus.

2. For the first time, the usefulness breast cancer screening in Belarus through self-examination and clinical examination has been justified from the economic point of view.

3. It was demonstrated for the first time on nationwide scale that early diagnosis of breast cancer by means of self-examination and clinical examination resulted in reduction of one-year mortality and disease-specific mortality.

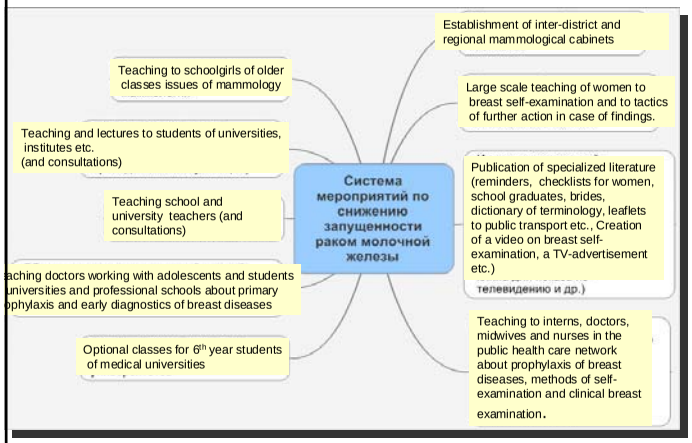
4. For the first time in Belarus, the population and their doctors were surveyed on the provision of breast care, and the subsequent analysis enabled the validation of the need for further improvements in the breast care service.

5. Algorithms of diagnosis of breast diseases and tactics of physicians in various forms of breast pathology were developed.

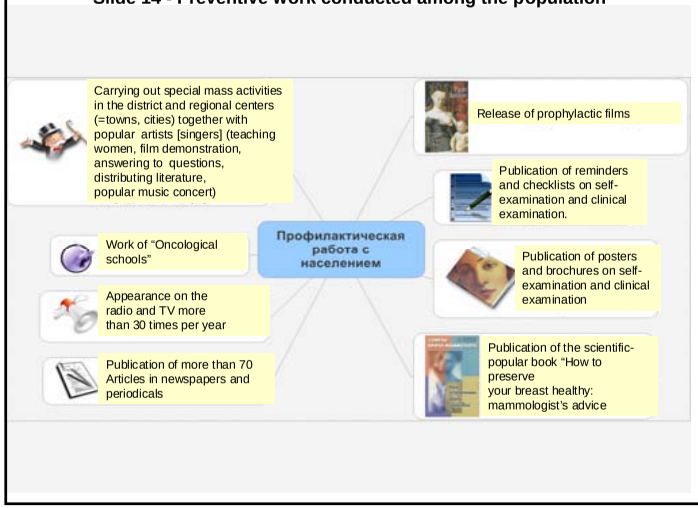
6. For the first time, the economic effect of cost reduction in the treatment of patients with primary breast cancer in the Republic of Belarus in connection with the reduction of [the proportion of] advanced cases was calculated.

For the organization and running of mammography screening during one year, according to our [=Belarusian] estimates, 144 billion roubles [about 36 million €] would be required, excluding the funds necessary to prepare the cabinets for the installation of stationary mammography machines, and all costs and difficulties associated with finding and training of medical personnel, especially for work in mobile mammography units.

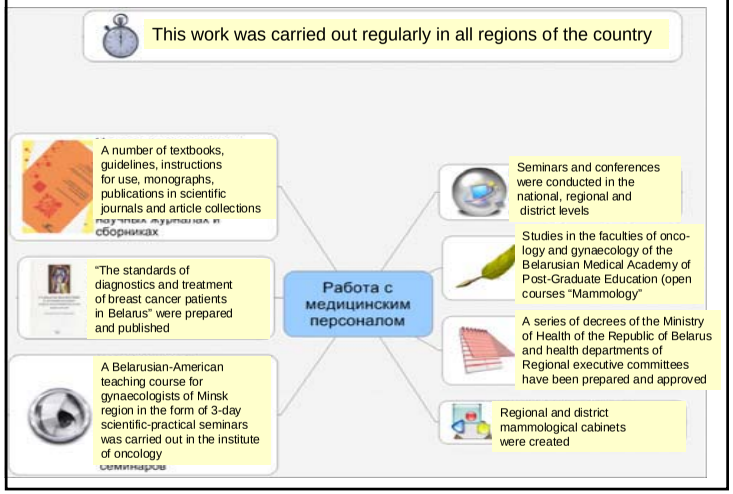
Slide 13 - The system of measures to reduce advanced breast cancer



Slide 14 - Preventive work conducted among the population



Slide 15 - Preventive of work conducted among medical personnel



Slide 16 – Results of the survey among the female population of the Republic of Belarus

✓ **86,7%** of women* were examined by a physician in a polyclinic or in a specialist obstetric-gynaecologic consultation unit during the last 12 months;

✓**76,0%** of respondents had been trained by their physician on the method of monthly breast self-examination;

[* From Q&A after the presentation 17.02.2011:
The questionnaire was sent to six thousand women. The response rate was 24%]

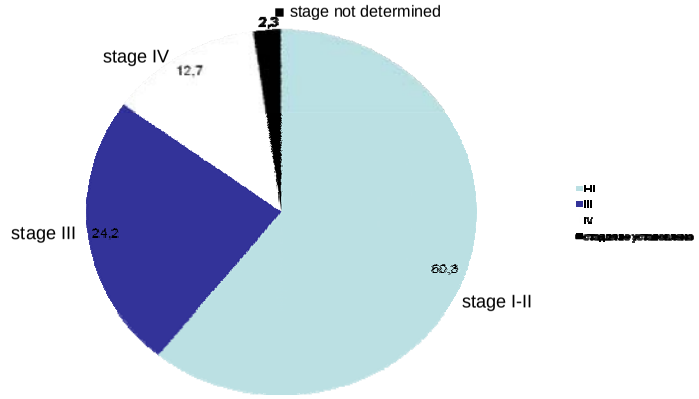
Slide 17 – Results of a survey among Belarusian physicians to determine their knowledge on methods of breast examination and their practical skills and quality of work in this area

- The majority of respondents (**83,9%**) considered that one examination per year for women is not [frequently] enough for early detection of breast cancer;
- **82,4%** of specialists considered that physicians of other specialities (in addition to gynaecologists and oncologists) should also examine women's breasts;
- **64,5%** of physicians (100% of obstetrician-gynecologists, 57,1% of internists and 61,5% of surgeons) palpated women's breasts;
- **53,8%** did not have sufficient palpation skills (70,7% of obstetrician-gynecologists, 37,4% of internists and 58,7% of surgeons);
- **55,5%** of physicians did not undergo further training on breast cancer prevention in post-graduate education institutions durling the last 5 years;
- **45,2%** of respondents had detected breast cancer in their clinical practice;

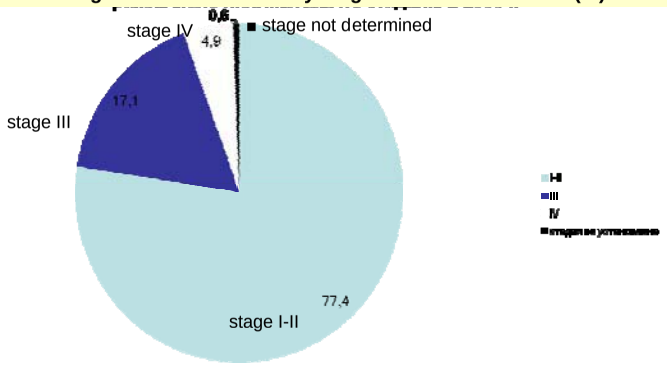
Slide 18 – Results of a survey among Belarusian physicians to determine their knowledge on methods of breast self-examination and their practical skills and quality of work in this area

- The majority (**61,3%**) considered that they do not have enough information materials in order to correctly explain to women about the importance of breast self-examination;
- The majority of specialists (**82,7%**) informed their patients about the need for breast self-examination;
- **93,9%** of female doctors performed breast self-examination;

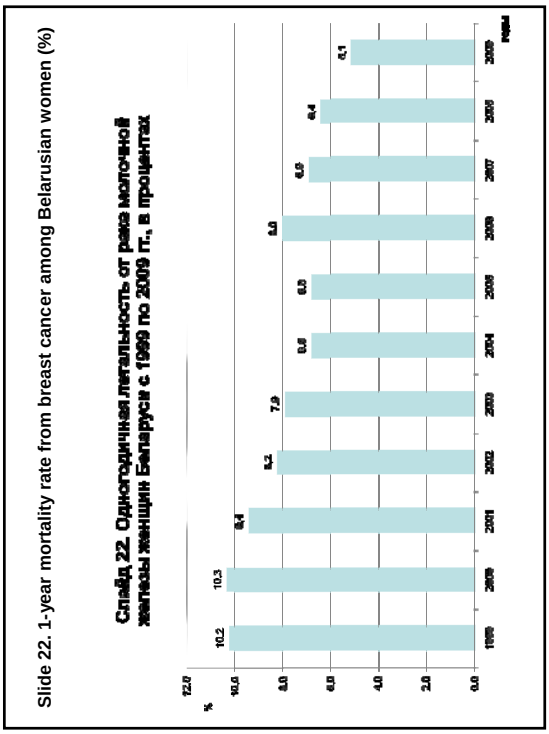
Slide 19. Stage distribution of newly diagnosed breast cancers (%) in 1994



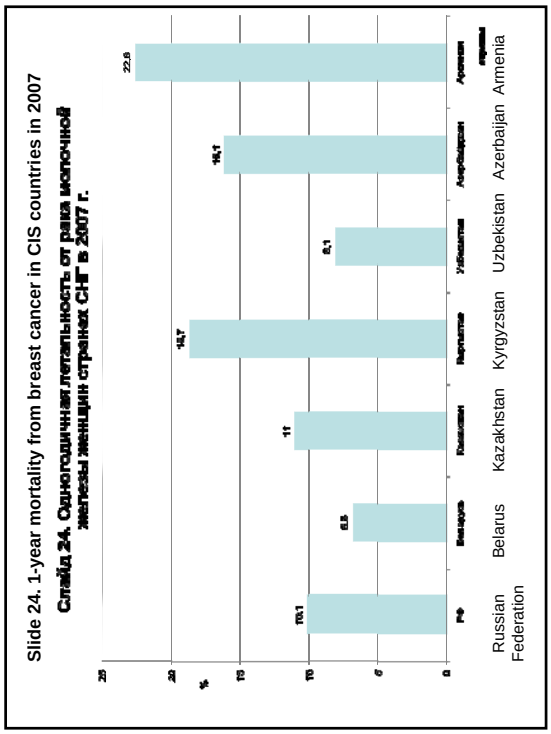
Slide 20. Stage distribution of newly diagnosed breast cancers (%) in 2009



Slide 22. 1-year mortality rate from breast cancer among Belarusian women (%)



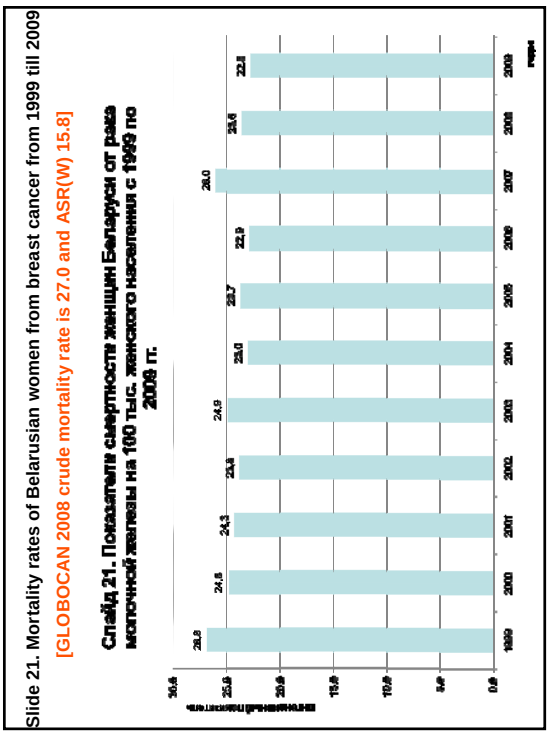
Slide 24. 1-year mortality from breast cancer in CIS countries in 2007



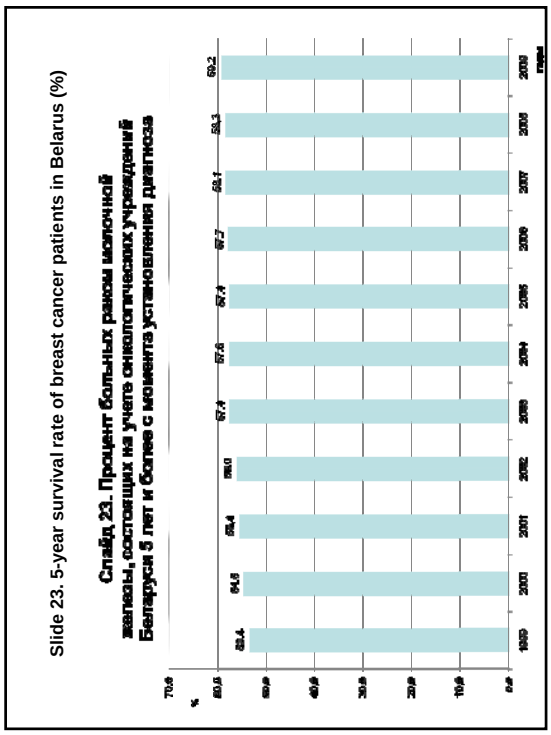
Russian Federation Belarus Kazakhstan Kyrgyzstan Uzbekistan Azerbaijan Armenia

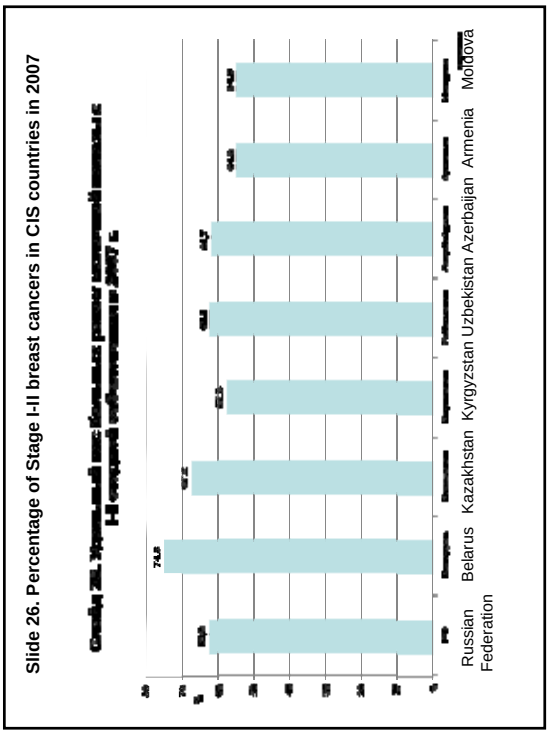
Slide 21. Mortality rates of Belarusian women from breast cancer from 1999 till 2009

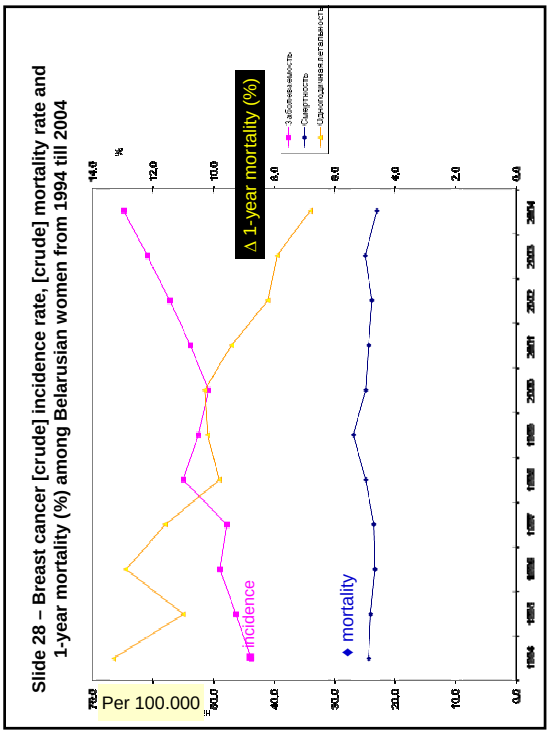
[GLOBOCAN 2008 crude mortality rate is 27.0 and ASR(W) 15.8]

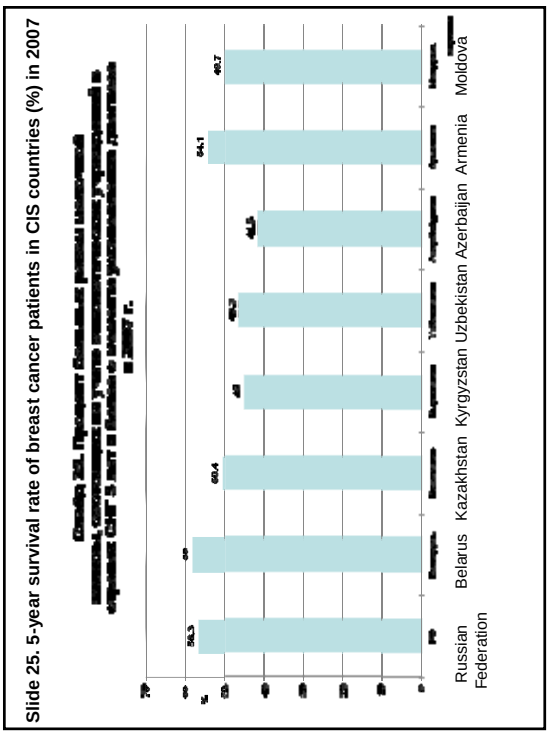


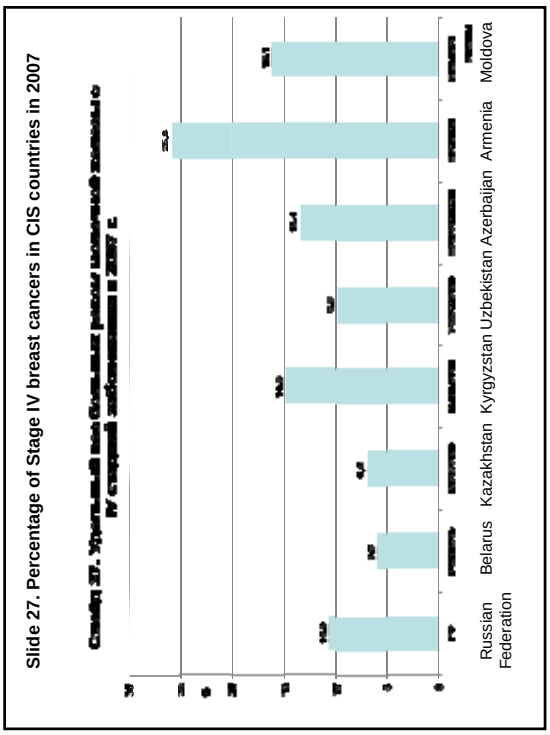
Slide 23. 5-year survival rate of breast cancer patients in Belarus (%)



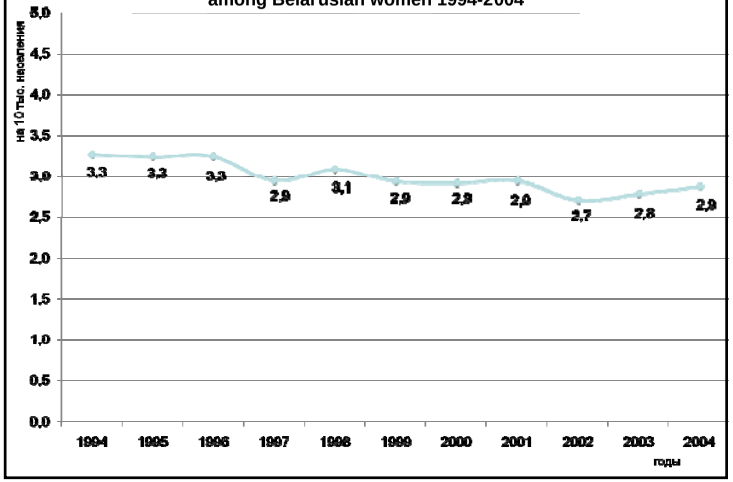

Slide 26. Percentage of Stage I-II breast cancers in CIS countries in 2007
74.8
Russian Federation
Belarus
Kazakhstan
Kyrgyzstan
Uzbekistan
Azerbaijan
Armenia
Moldova


Slide 28 – Breast cancer [crude] incidence rate, [crude] mortality rate and 1-year mortality (%) among Belarusian women from 1994 till 2004
Per 100.000
incidence
mortality
Δ 1-year mortality (%)

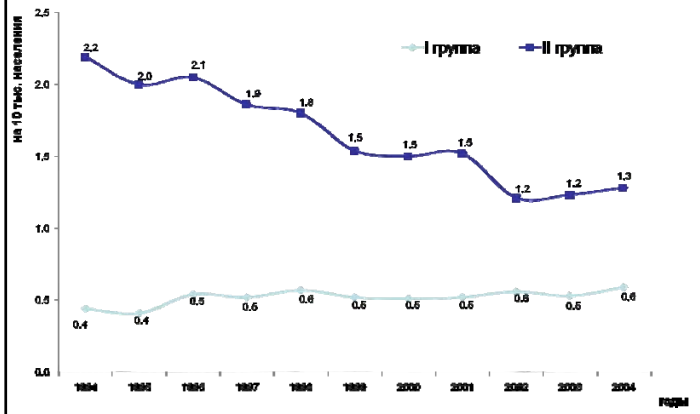

Slide 25. 5-year survival rate of breast cancer patients in CIS countries (%) in 2007
Russian Federation
Belarus
Kazakhstan
Kyrgyzstan
Uzbekistan
Azerbaijan
Armenia
Moldova


Slide 27. Percentage of Stage IV breast cancers in CIS countries in 2007
Russian Federation
Belarus
Kazakhstan
Kyrgyzstan
Uzbekistan
Azerbaijan
Armenia
Moldova

Slide 29 – Primary disability index (per 10 000 population) from breast cancer among Belarusian women 1994-2004



Slide 30 – rates [per 10.000 population] of 2nd and 3rd groups of disability from breast cancer among Belarusian women 1994 - 2004



The work to decrease advanced breast cancer in the Republic of Belarus showed an economic impact on the costs of treatment **during one year** equal to **3 billion 170 million** Belarusian roubles. [about 800.000 €]

Conclusions:

1. For the first time in the Republic of Belarus and CIS countries, a comprehensive method of breast cancer screening through self-examination and clinical examination was developed and introduced into clinical practice, which in 11 years has lowered the share of advanced breast cancer in Belarus by 47.5% (from 39,6% in 1994 was to 20.8% in 2004).

2. For the first time in the Republic of Belarus, the usefulness of screening for breast cancer through self-examination and clinical examination was justified from an economic point of view, because the cost of establishing annual mammographic screening in Belarus and paying for one year's work is 195 billion roubles [over 48 million €], excluding funds required to prepare cabinets for the installation of stationary mammography machines, and all costs associated with finding and training of medical personnel.

Conclusions:

3. For the first time in the country-wide scale it has been proven that breast cancer screening by self-examination and clinical examination reduced 1-year mortality rate by 48,8% (from 13,3% in 1994 to 6,8% in 2004) and increased 5-year survival rate by 6,7% (from 54,0% in 1994 to 57,6% in 2004).

4. The introduction of methods of self-examination and clinical examination resulted in a decrease in the primary disability index among women with breast cancer (from 3,27 in 1994 to 2,87 per 10 thousand population in 2004), mostly due to a decrease among working age women (from 2,76 in 1994 to 2,52 per 10 thousand population in 2004). A decrease in the severity of disability was noted, due to a decrease in 2nd degree disability (from 2,19 in 1994 to 1,28 per 10 thousand population in 2004) and an increase in 3rd degree disability (from 0,63 to 0,99 per 10 thousand population).

Conclusions:

5. The analysis of a survey among general practitioners showed that following the work undertaken during 10 years, the majority of doctors (83,9%) are aware of the importance of self-examination and clinical examination of the mammary glands of women in the timely diagnosis of breast cancer. So far, however, not all specialists (37.4% internists, 58.7% of surgeons, 70.7% of obstetricians and gynecologists) have sufficient knowledge and relevant literature for successful work in this field. It was noted that 66.3% of obstetrician-gynecologists, 41.6% internists and 36.5% of surgeons attended training seminars on mammology.

Conclusions:

6. The analysis of survey of the female population of Belarus in 2004 showed that 86.7% of women were examined by doctors over the past 12 months. 76.04% of women have been trained into the method of monthly breast self-examination.

7. The cost reduction in treatment of patients with primary breast cancer from reducing advanced cancer in Belarus amounted to 3 billion 170 million rubles [about 800.000 €] in the year 2004 only.

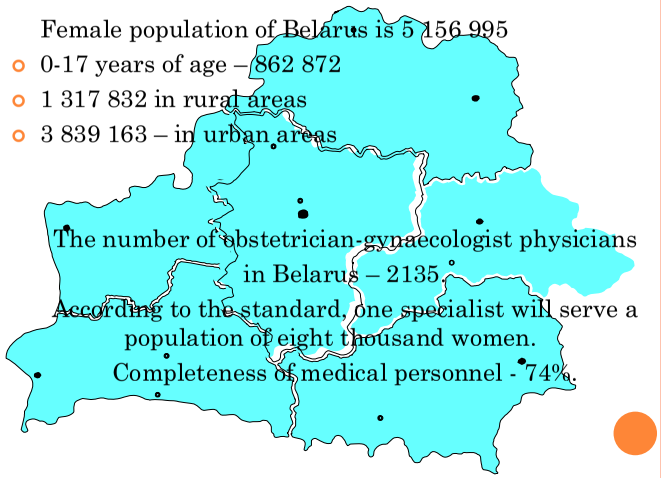
THANK YOU FOR YOUR ATTENTION

CERVICAL CANCER IN THE REPUBLIC OF BELARUS

Litvinova, Tatiana Mikhailovna
MD, PhD. Chief research fellow of the Department of Gynecological Oncology
N.N. Aleksandrov Research Centre and Clinic for Oncology and Medical Radiology

Female population of Belarus is 5 156 995

- 0-17 years of age – 862 872
- 1 317 832 in rural areas
- 3 839 163 – in urban areas



The number of obstetrician-gynaecologist physicians in Belarus – 2135.
According to the standard, one specialist will serve a population of eight thousand women.
Completeness of medical personnel - 74%.

Cancer incidence distribution by site in Belarus for 2010

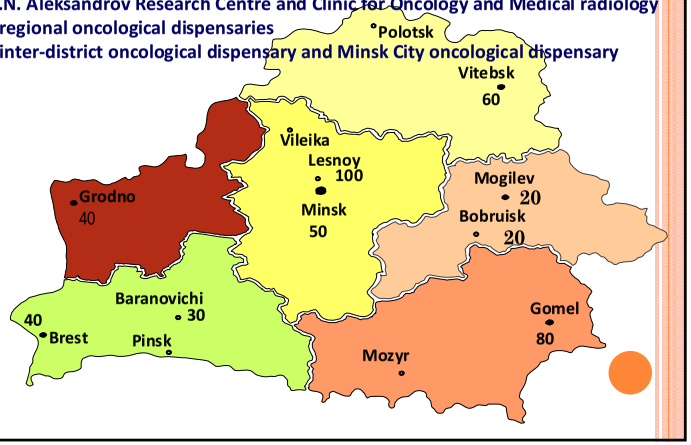
Localisation	Males		Females	
Lung	18,1		2,7	
Large bowel	9,7	19,4%	10,6	16,7%
Stomach	8,5		6,1	
Breast	0,2		17,6	
Prostate	13,7 (5,5% - 1996 г.)	23,1%		
Kidney	4,9		3,5	4,7%
Bladder	4,5		1,2	
Uterine corpus			7,8	16,5%
Uterine cervix			4,3	
Ovaries			4,4	
Skin	13,8		20,1	
Others	26,6		21,9	

Organs of the reproductive system- 34,1%

Data of Belarusian Cancer Registry, 2010

Gynaecological oncology service in Belarus: 440 beds in specialist hospitals

N.N. Aleksandrov Research Centre and Clinic for Oncology and Medical radiology
5 regional oncological dispensaries
1 inter-district oncological dispensary and Minsk City oncological dispensary

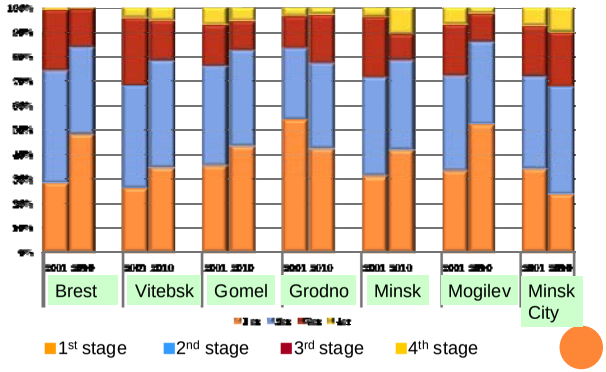


CERVICAL CANCER IN B

- World age-standardised incidence rate is 12,5
- Crude incidence 17,3 per 100 000 women
- Annual absolute incidence is 720 - 1000 women
- Among incidence cases stage III-IV share is 20-25%
- World age-standardised mortality rate is 4,0
- Crude mortality is 6,2 per 100 000 women
- Annual absolute mortality is 300-350 women

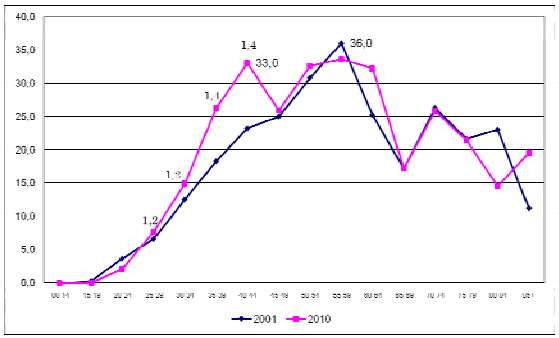
- Every day one woman in Belarus dies from cervical cancer. Every two days five women are diagnosed with cervical cancer

DISTRIBUTION OF INCIDENT CASES OF CERVICAL CANCER BY STAGE (%) AND BY REGION in 2001 and 2010

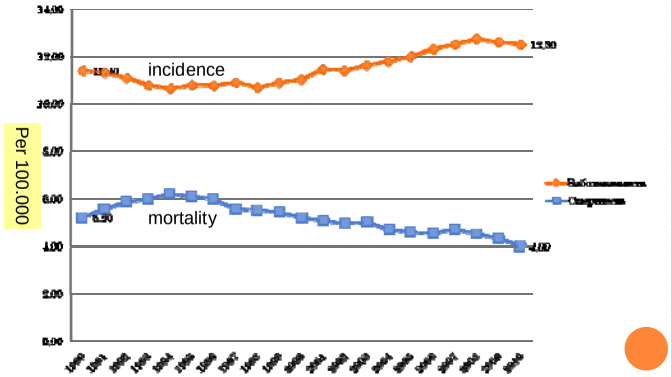


In 2010, 76,9% were stage I-II and 23,1% were stage III-IV.

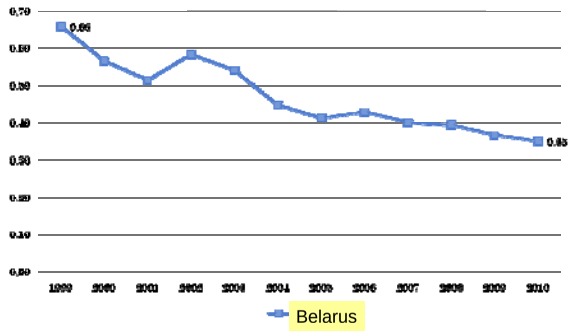
INCIDENCE OF CERVICAL CANCER IN BELARUS BY AGE GROUP IN 2001 AND 2010



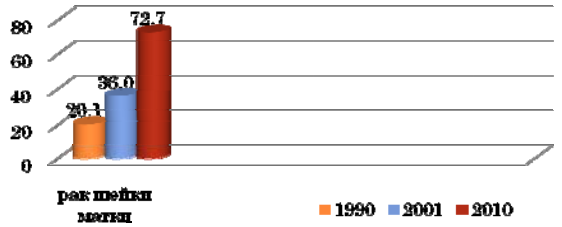
Cervical cancer incidence and mortality from 1990 till 2010, world age-standardized rates



Mortality/incidence ratio of cervical cancer from 1999 till 2010

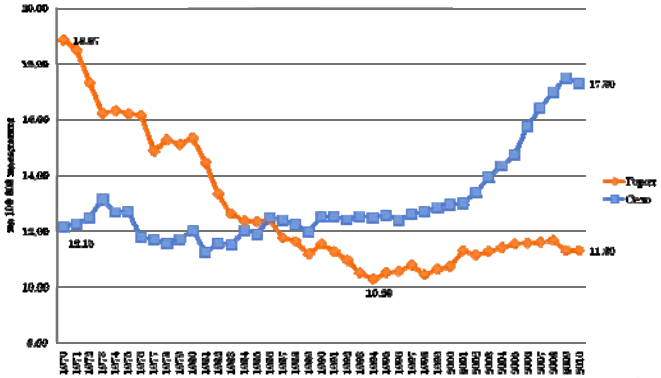


Frequency of cervical cancers diagnosed at prophylactic examinations in Belarus during 1990, 2001 and 2010 (%)



1990: 159/793 cervical cancers were detected at prophylactic examinations
2001: 285/791 cervical cancers were detected at prophylactic examinations
2010: 665/915 cervical cancers were detected at prophylactic examinations

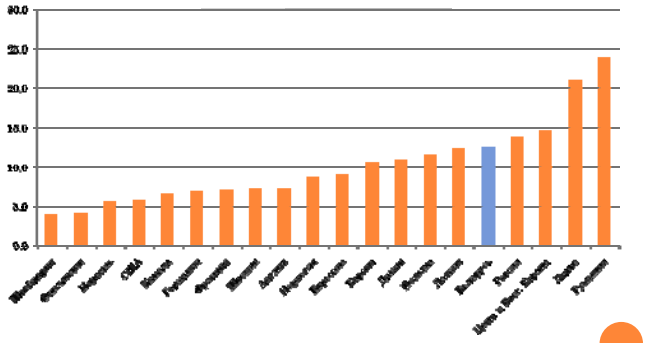
World age-standardised incidence rates of cervical cancer in urban (orange) and rural (blue) areas

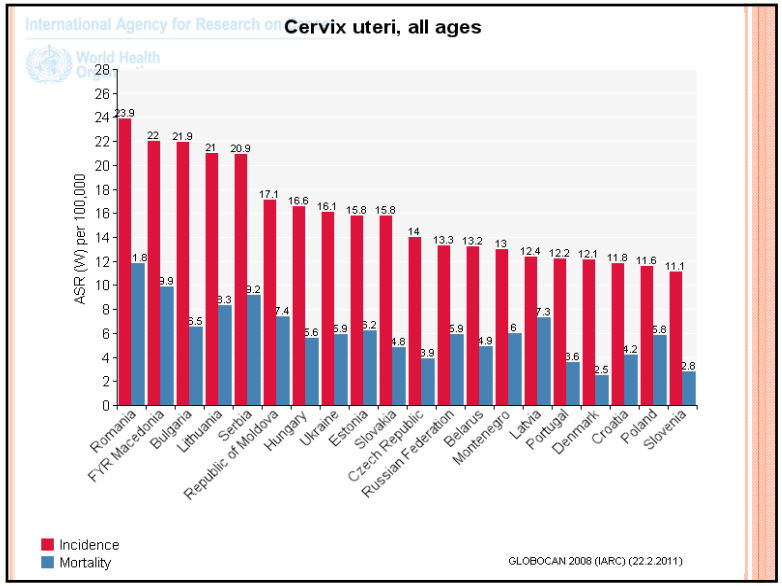


During 25 years (1970-1994), due to prophylactic examinations among the urban population, cervical cancer incidence fell by 45,7%

Cervical cancer incidence (GLOBOCAN 2008)

[Higher than Belarus: Russia, Central and Eastern Europe, Lithuania, Romania
Lower than Belarus: Latvia, Poland, Denmark, Europe, EU, Norway, England, Sweden, France, Germany, Canada, USA, Israel, Finland, Switzerland]




International Agency for Research on
Cervix uteri, all ages
World Health Organization
ASR (W) per 100,000
28
26
24
22
20
18
16
14
12
10
8
6
4
2
0
23.9
1.8
22
9.9
21.9
6.5
21
8.3
20.9
9.2
17.1
7.4
16.6
5.6
16.1
5.9
15.8
6.2
15.8
4.8
14
3.9
13.3
5.9
13.2
4.9
13
6
12.4
7.3
12.2
3.6
12.1
2.5
11.8
4.2
11.6
5.8
11.1
2.8
Romania
FYR Macedonia
Bulgaria
Lithuania
Serbia
Republic of Moldova
Hungary
Ukraine
Estonia
Slovakia
Czech Republic
Russian Federation
Belarus
Montenegro
Latvia
Portugal
Denmark
Croatia
Poland
Slovenia
Incidence
Mortality
GLOBOCAN 2008 (IARC) (22.2.2011)


Благодарю за
внимание

ГУ «РЕСПУБЛИКАНСКИЙ НАУЧНО-ПРАКТИЧЕСКИЙ ЦЕНТР ОНКОЛОГИИ И МЕДИЦИНСКОЙ РАДИОЛОГИИ им. Н.Н. АЛЕКСАНДРОВА»

CYTOLOGICAL PRACTICE IN MEDICAL EXAMINATION OF FEMALE POPULATION OF THE REPUBLIC OF BELARUS

L.B. KLUKINA, O.A. EROKHINA

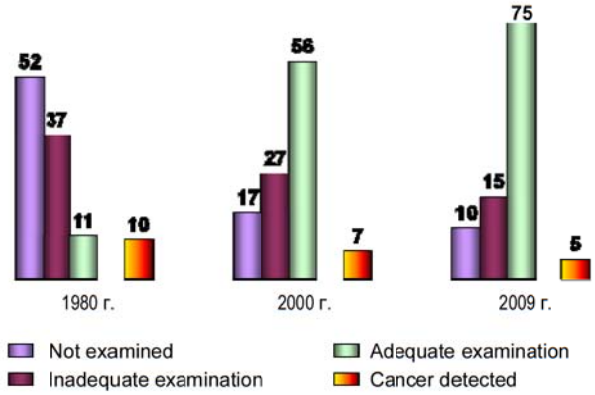
THE USE OF CYTOLOGY IN PROPHYLACTIC EXAMINATIONS OF WOMEN

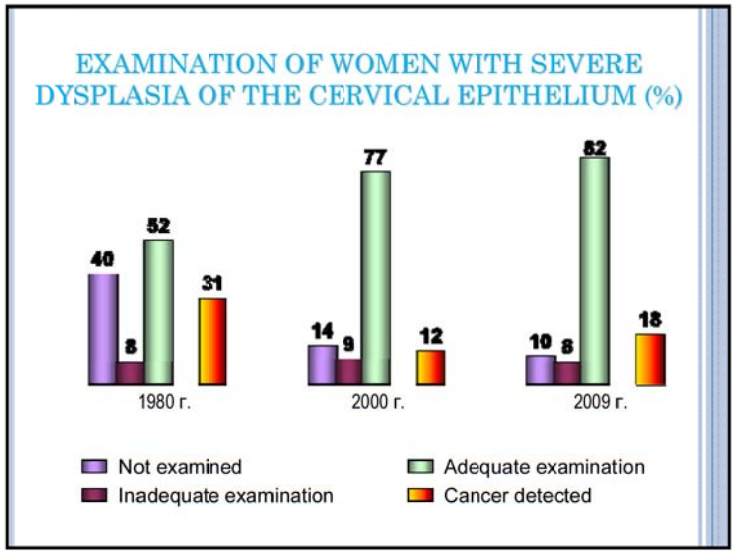
Women examined (%)*

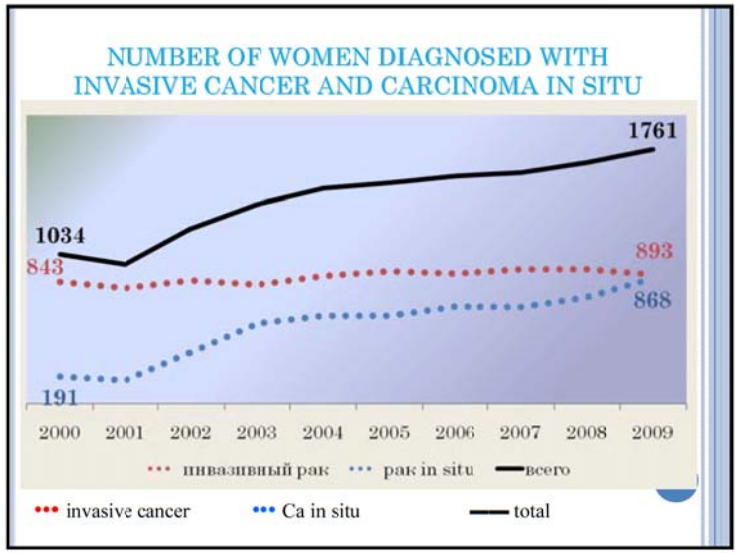
REGION	1979	1990	2000	2009
Brest	12,5	90,1	88,3	92,3
Vitebsk	13,5	63,1	66,7	94,4
Gomel	8,1	67,5	73,8	75,0
Grodno	44,0	89,3	95,3	94,4
Minsk	7,3	81,5	82,6	93,5
Mogilev	26,7	80,7	86,7	88,2
City of Minsk	21,7	819	67,7	81,2
BELARUS	**17,9**	80,3	79,3	**88,0**

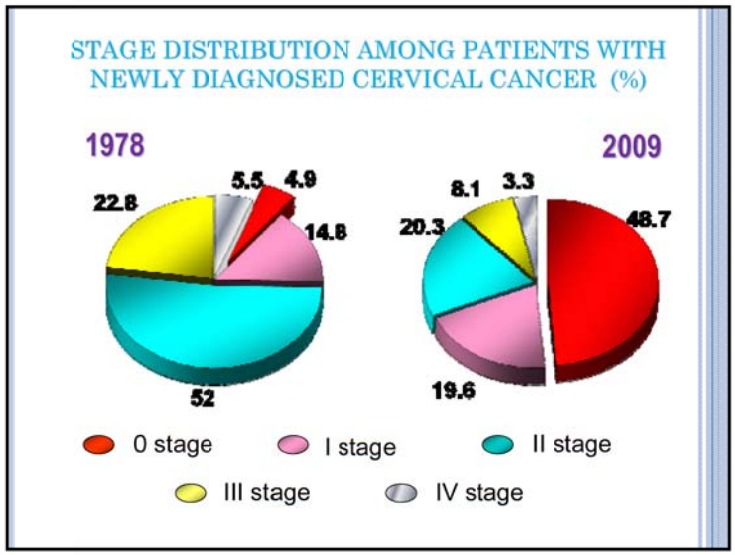
*The real percentage is lower since the count is non-personal.

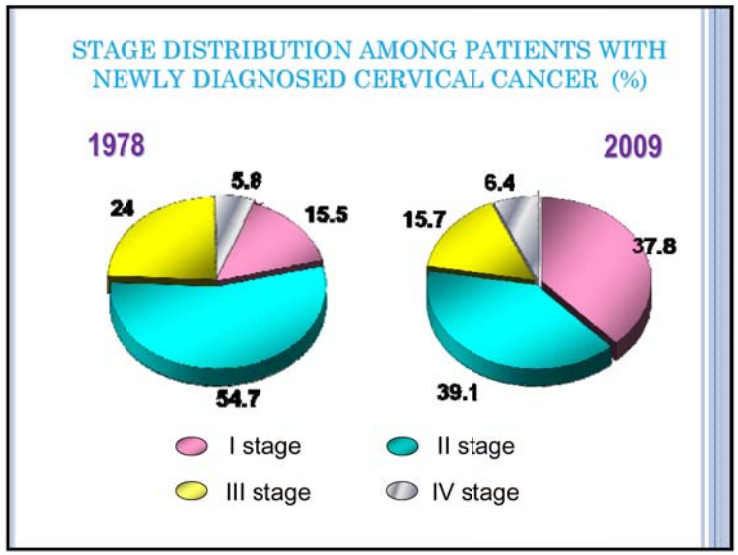
EXAMINATION OF WOMEN WITH MODERATE DYSPLASIA OF CERVICAL EPITHELIUM (%)




EXAMINATION OF WOMEN WITH SEVERE DYSPLASIA OF THE CERVICAL EPITHELIUM (%)
40
8
52
31
14
9
77
12
10
8
82
18
1980 г.
2000 г.
2009 г.
Not examined
Inadequate examination
Adequate examination
Cancer detected


NUMBER OF WOMEN DIAGNOSED WITH INVASIVE CANCER AND CARCINOMA IN SITU
1761
1034
843
893
868
191
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009
инвазивный рак
рак in situ
всего
invasive cancer
Ca in situ
total


STAGE DISTRIBUTION AMONG PATIENTS WITH NEWLY DIAGNOSED CERVICAL CANCER (%)
1978
2009
22.8
5.5
4.9
14.8
52
8.1
3.3
20.3
48.7
19.6
0 stage
I stage
II stage
III stage
IV stage


STAGE DISTRIBUTION AMONG PATIENTS WITH NEWLY DIAGNOSED CERVICAL CANCER (%)
1978
2009
24
5.8
15.5
54.7
15.7
6.4
37.8
39.1
I stage
II stage
III stage
IV stage

Control of breast and cervical cancer in Belarus

Current status and prospects for future improvement with special attention to population-based screening programmes

Implementation of Cancer Screening in the European Union

Lawrence von Karsa
Quality Assurance Group
Section of Early Detection and Prevention

International Agency for Research on Cancer
Lyon, France

The European Union today

- 500 million population
  - 136 million men and women 50-74 yrs.
  - 109 million women 30-60 yrs.
  - 59 million women 50-69 yrs.
- 27 Member States
  - **15 acceded before 2004**
    Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
  - **12 recently acceded in 2004 and 2007**
    Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovak Republic, Slovenia,

International Agency for Research on Cancer
World Health Organization

THE COUNCIL OF THE EUROPEAN UNION

Recommendation on Cancer Screening of
2 December 2003

Over 30 specific recommendations

- Based on:
  - WHO principles of cancer screening (Wilson and Jungner)
  - Experience in implementing cancer screening programmes in EU member states
- Covering how to:
  - implement cancer screening programmes
  - maintain appropriate quality of screening programmes
  - reach appropriate decisions on new or modified programmes

International Agency for Research on Cancer
World Health Organization

THE COUNCIL OF THE EUROPEAN UNION

Recommendation on Cancer Screening of
2 December 2003

1. Implementation of cancer screening programmes

(a) Offer evidence-based cancer screening through a systematic *population-based* approach with *quality assurance at all appropriate levels*. The tests which should be considered in this context are listed in the Annex;

(b) Implement screening programmes in accordance with *European guidelines* on best practice where they exist and facilitate the further development of best practice for high quality cancer screening programmes on a national and, where appropriate, regional level;

International Agency for Research on Cancer
World Health Organization

THE COUNCIL OF THE EUROPEAN UNION

Recommendation on Cancer Screening of
2 December 2003

HEREBY INVITES THE COMMISSION:

7. To report on the implementation of cancer screening programmes, on the basis of the information provided by Member States, not later than the end of the fourth year after the date of adoption of this Recommendation, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action.

ANNEX:

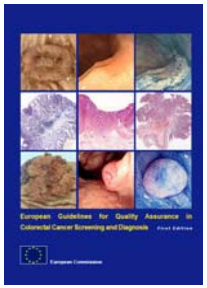
- **pap smear screening for cervical cancer** precursors starting not before the age of 20 and not later than the age of 30;
- **mammography screening for breast cancer** in women aged 50 to 69 in accordance with European guidelines on quality assurance in mammography;
- **faecal occult blood screening for colorectal cancer** in men and women aged 50 to 74.

International Agency for Research on Cancer
World Health Organization

EU Guidelines for Breast, Cervical and Colorectal Cancer Screening

4th Edition
2006[a)]

2nd Edition
2008[a)]



1st Edition
2010[b)]

Financial support through: [a)]EU Health Programme, [b)]UEGF, ACS, CDC

International Agency for Research on Cancer
World Health Organization

Need for Quality Assurance in Cancer Screening

- Screening is for predominantly healthy populations.
- The needs and concerns of healthy clients differ significantly from those of patients.
- The vast majority of clients are healthy - only a few will have a health benefit from screening.
- All clients are exposed to the risks of screening.
- The risks, even if only slight, may collectively shift the balance between harm and benefit into an inappropriate range.

International Agency for Research on Cancer
World Health Organization

Organized, Population-based Screening Preferred

- Infrastructure of organized programmes facilitates QA.
  - Individual data for monitoring / auditing
  - Linkage with cancer registries for evaluation
- Nationwide implementation of population-based programmes makes services performing to the high multidisciplinary standards accessible to the entire eligible target population.
- Large numbers of professionals undertake further specialisation in order to meet the screening standards.
- These nationwide efforts also lead to widespread improvement in diagnosis and management of cancers detected outside of screening programmes.

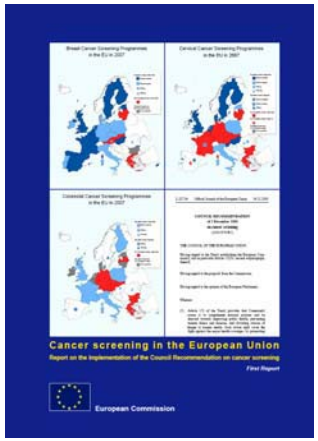
International Agency for Research on Cancer
World Health Organization

Approach to Guideline Development

- Comprehensive and multidisciplinary, covering entire process:
  - information and invitation of target population
  - performance of screening test
  - diagnostic work-up of test positives
  - treatment of screen-detected lesions
- Programmatic issues – documentation, monitoring, evaluation, training, implementation, communication
- Experience-based – expert consensus (breast/cervical)
- Evidence-based – systematic review (CRC)

International Agency for Research on Cancer

World Health Organization



Cancer Screening in the European Union

Report on the implementation of the Council Recommendation on cancer screening *First Report*

L v Karsa, A Anttila, G Ronco, A Ponti, N Malila, M Arbyn, N Segnan, M Castillo-Beltran, M Boniol, J Ferlay, C Hery, C Sauvaget, L Voti, P Autier

http://bookshop.eu.int/eGetRecords?Template=Test_EUB/en_publication_details&CATNBR=ND7306954ENC

Financial support of EU Health Programme (ECN/EUNICE/ECCG)

International Agency for Research on Cancer

World Health Organization

Report on the implementation of the Council Recommendation on cancer screening - *First Report* Screening Programme Type

1. **Programme screening** requires public responsibility, coordination, supervision. The screening policy should at least
   - Be defined by law or *official* regulation, decision, directive or recommendation
   - Specify screening test, examination interval, eligible group of persons
   - Provide for public financing of participation in screening (apart from own contribution)

   Note: In many countries, in addition to programme screening, significant volumes of "wild" screening may be performed, outside of any programme. Such activities were not covered..

International Agency for Research on Cancer

World Health Organization

Report on the implementation of the Council Recommendation on cancer screening - *First Report* Screening Programme Type, cnt'd

2. **Organised Screening** (not used to classify programmes because the degree of organisation varies widely):

   In addition to the targeted population group(s), the screening test, and the examination interval(s) programme policy generally
   - Provides for national or regional team responsible for implementation (coordinating service delivery, quality assurance, and reporting of performance and results)
   - Requires comprehensive guidelines, rules and standard operating procedures
   - Defines a quality assurance structure and mandates supervision and monitoring of most steps in the screening process
   - Requires ascertainment of the population disease burden

International Agency for Research on Cancer

World Health Organization

Report on the implementation of the Council Recommendation on cancer screening - *First Report*
Screening Programme Type, cont'd

3. **Population-based screening** generally requires a high degree of organisation in order to
   - Identify and invite each person in the eligible target population (promotes equality in access to health care)
   - Assure that the invitational activities are performed reliably and effectively and are adequately coordinated with the subsequent steps in the screening process

Note: The organisational infrastructure of population-based screening programmes is conducive to implementation of quality assurance and evaluation – such as by facilitating linkage of screening data and cancer registry data.

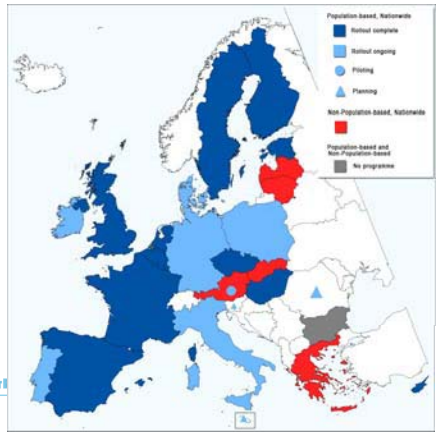
International Agency for Research on Cancer
World Health Organization

Report on the implementation of the Council Recommendation on cancer screening - *First Report*
Country Implementation Status

1. **Programme or No Programme**
2. **Nationwide or Regional** (aim of public screening policy)
3. **If Programmes are Population-Based**
   - Pilot phase
   - Planning phase
   - Rollout ongoing: at least some invitations have been sent
   - Rollout complete (fully established)
     - At least ca. 90% of eligible target population in respective country or region personally invited at least once
     - All elements of screening process are fully functional
   - Mixed: different phases in various regions of the country

International Agency for Research on Cancer
World Health Organization

BREAST Cancer Screening Programmes in the EU in 2007



Sources:
Karsa, Anttila, Ronco et al. 2008, European Commission, IARC, ECN and EUNICE
Financial support of EU Public Health Programme

International Agency for Research on Cancer
World Health Organization

CERVICAL Cancer Screening Programmes in the EU in 2007

Sources:
Karsa, Anttila, Ronco et al. 2008, European Commission, IARC, ECN and EUNICE
Financial support of EU Public Health Programme

International Agency for Research on Cancer
World Health Organization

Number of Countries with Breast, Cervical or CRC Screening Programmes in the EU by Programme Type and estimated % of Minimum Recommended Target Population in the EU in 2007*

Type	Breast Cancer		Cervical Cancer		Colorectal cancer	
	Number of countries	Women 50-69 yrs. (59×10^6)	Number of countries	Women 30-60 yrs. (109×10^6)	Number of countries	Women / Men 50-74 yrs. (136×10^6)
Population-based	22	91.5 %	15	50.5 %	12	42.6 %
Non-population-based	5	6.2 %	12	47.4 %	7	27.4 %
No programme	1	1.8 %	2	0.2 %	8	8.3 %

* Nos. do not add up to 27 due to dual status of breast and cervical cancer screening in 1 and 2 countries, respectively.
Percents do not add up to 100% due to excluded regions or age groups in some countries

International Agency for Research on Cancer
World Health Organization

COLORECTAL Cancer Screening Programmes in the EU in 2007

FOBT-based programmes

Sources:
Karsa, Anttila, Ronco et al. 2008, European Commission, IARC, ECN and EUNICE
Financial support of EU Public Health Programme

International Agency for Research on Cancer
World Health Organization

Colorectal Cancer Screening Programmes in the EU 1/2011

Population-based	Non population-based	No programme
Belgium *	Austria	Estonia
Cyprus	Bulgaria	Luxembourg
Denmark*	Czech Rep.	Netherlands
Finland	Germany	
France	Greece	
Hungary	Latvia	
Ireland*	Poland	
Italy	Slovak Rep.	
Lithuania		
Malta*		
Portugal		
Romania		
Slovenia		
Spain		
Sweden		
UK		

FOBT-based	FOBT/CS-based	FOBT/FS-based	CS-based	No programme
Bulgaria	Austria	Italy	Poland	Estonia
France	Belgium			Luxembourg
Finland	Cyprus			Netherlands
Hungary	Czech Rep.			
Ireland	Denmark			
Latvia	Germany			
Lithuania	Greece			
Malta	Slovak Rep.			
Portugal				
Romania				
Slovenia				
Spain				
Sweden				
UK				

International Agency for Research on Cancer
World Health Organization

Report on the implementation of the Council Recommendation on cancer screening - *First Report*

- All Member States aim to follow EU quality assurance guidelines
- Over 50 population-based programmes for breast, cervical, or colorectal cancer screening running or being established in 26 Member States
- Already over 500 million screening examinations in 10-year period. (over 100 million CRC screening tests)
- Need for professional, technical and scientific support for quality assurance, monitoring, evaluation and accreditation
- Adequate resources, including expanded international collaboration, are essential

International Agency for Research on Cancer
World Health Organization

Financial support of EU Health Programme (ECN/EUNICE/ECCG)

Implementation of cancer screening programmes
Minimum requirements

- Strong political support and adequate long-term funding
- Adequate planning, testing, and modification prior to rollout
- Training of all staff, specialisation, observance of volume levels
- Multidisciplinary teamworking
- Population-based invitation and evaluation
- Quality-driven management structure with coordination at national, regional and local level
- Setting targets, monitoring and continuous improvement of all activities in the entire screening process based on internationally recognized standards
- International cooperation and collaboration in implementation, quality assurance, monitoring and evaluation

International Agency for Research on Cancer
World Health Organization

*Source: L. von Karsa, Quality Assurance Group, Prevention and Early Detection Section, International Agency for Research on Cancer

Sequence of Steps in Quality-controlled Implementation of Screening Programmes*

1. Comprehensive **planning** of screening process: feasibility of screening models, professional performance, organisation and financing, quality assurance (QA)
2. Preparation of all components of screening process to perform at requisite high level (including **feasibility testing**)
3. Expert **verification** of adequacy **of preparations**
4. **Piloting** and modification, if necessary, of all screening systems and components, including QA, in routine settings
5. Expert **verification** of adequacy **of pilot performance**
6. Transition of pilot to service screening and geographically phased **programme rollout** in other regions of the country
7. Intensive **monitoring of programme rollout** for early detection and correction of quality problems

International Agency for Research on Cancer
World Health Organization

*Source: L. von Karsa, Quality Assurance Group, Prevention and Early Detection Section, International Agency for Research on Cancer

Quality-assured implementation of cancer screening programmes
Preparing a decision to begin programme implementation

1. Political will, commitment, at all relevant levels (national, regional, local)
2. Understanding of the role of population-based screening in cancer control
3. Economic impact and cost-effectiveness of the programme
4. Formal decision and allocation of budget
5. Build up a professional and public understand of the benefits and risks of screening
6. Coaching
7. Guidelines
8. Background information

International Agency for Research on Cancer
World Health Organization

*Source: Preliminary results of EUSAN-ISO workshop 7-9 February

Comprehensive planning of screening process: feasibility of screening models, professional performance, organisation and financing, quality assurance (QA)

1. Programme implementation begins with the appointment of a coordinating director
    - Mandate to manage the process of programme implementation
    - Planning all aspects
    - Budgetary control
    - Appointment and management of dedicated staff
    - Official oversight
2. Prepare piloting (e.g. by developing and testing screening model)
3. Develop professional performance (training)
4. Organisational and financial aspects
5. Develop and test comprehensive quality assurance programme

International Agency for Research on Cancer
World Health Organization

*Source: Preliminary results of EUSAN-ISO workshop 7-9 February 2011

Thank you for your attention

IARC Handbook of Cancer Prevention Breast Cancer Screening - 2002

Level of evidence for efficacy of breast cancer screening (sole modalities)

- Mammography
  - 50-69 yrs: sufficient
  - 40-49 yrs: limited
  - <40 or >69 yrs: inadequate
- Clinical breast examination: inadequate
- Breast self-examination: inadequate

IARC Handbook of Cancer Prevention Breast Cancer Screening - 2002

Implications for public health

- Mammography is the only intervention which can be recommended for breast cancer screening
- Mammography screening programmes can be recommended for women aged 50-69 years
  - Expected breast cancer mortality reduction in participants – approx. 35%
  - Expected breast cancer mortality reduction in invited population – approximately 20%
  - Lower impact can be expected if opportunistic screening is widespread prior to introduction of programme

Recent Publications Updating Evidence on Effectiveness of Breast Screening Programmes

- Brief overview in Chapter on Breast Cancer Screening in IARC 2008 World Cancer Report
- Cancer Epidemiol Biomarkers Prev 2006; 15(1):45-51
  - Swedish Organized Service Screening Evaluation Group (>0.5 million women each in pre-screening and screening epochs)
  - 40-69-year-old women - 40-45% breast cancer mortality reduction (27% in screened population)
- Hellquist et al. 2010 (Cancer)
  - Swedish Mammography Screening in Young Women (SCRY) Cohort (control group > 8 mil. per.-yrs, screening group > 7 mil. per.-yrs)
  - 40-49-year-old women - 29% breast cancer mortality reduction (26% in screened population). Effect higher 45-49-yrs

Nationwide Mammography Screening: Major Issues associated with Introduction of the Program

Peter B. Dean, MD
Professor of Radiology
University of Turku, Finland
Director of Breast Imaging
Turku University Hospital

Design of the Breast Cancer Screening Program

- **Age limits**: Currently 50-69, but with eventual expansion to 40-74+
- **Two-year interval** between screens
- **Independent double reading** of all screening images by two radiologists, with consensus review in all cases of discrepancy
- **Evaluation of all recalled women** by the screening radiologists

Interdisciplinary Conferences

- Including pathologists, radiologists, surgeons, oncologists, radiographers, breast nurse
- Preoperative meeting(s) for all patients
- Specimen radiography of operative specimens to assist the pathologist in determining full tumor extent and margins
- Postoperative meeting(s) for all patients

Preparation for Screening

- Necessary to increase capacity of diagnostic imaging, including mammography, ultrasound, image-guided core needle biopsy and breast MRI
- Training of more radiologists to handle the greater workload to be produced by screening as full-time breast radiologists
- Teaching these same radiologists how to screen

Quality Control

- Whenever a cancer is detected on screening, the previous films should be checked to see if the cancer could have been detected earlier, and to learn not to miss similar types
- When delays occur, find out the reason, and try to prevent similar delays in the future
- Whenever the surgical margin is not clean, the cause should be found and corrected
- Communication problems may prevent the patient from receiving proper care – good teamwork is very important to prevent them

Screening is not for every radiologist

- Screening can be learned from an experienced teacher
- To become a good screener, it is necessary to review the pathology of the patients sent to surgery, and to review the mammograms of the cancers that have been missed
- Starting screening with training and coaching by an experienced teacher is recommended because mistakes can be avoided

A Special Advantage for Belarus

- Potential for domestic development and production of a highly advanced mammography device using the most modern technology

Control of breast and cervical cancer in Belarus. Current status and prospects for future improvement with special attention to population based screening programmes

February 17, 2011, Minsk

About cervical cancer screening guidelines

E. Suonio, MD
Quality Assurance Group
Early Detection and Prevention Section

International Agency for Research on Cancer

World Health Organization

Key points

- Evidence based screening
- Population based approach
- Comprehensive quality assurance
- International collaboration in
  - planning
  - feasibility testing
  - piloting
  - program implementation

International Agency for Research on Cancer

World Health Organization

PRINCIPLES AND PRACTICE OF SCREENING FOR DISEASE

J. M. G. WILSON
Principal Medical Officer, Ministry of Health, London, England

G. JUNGNER
Chief, Clinical Chemistry Department, Sahlgren's Hospital, Gothenburg, Sweden

WORLD HEALTH ORGANIZATION
GENEVA
1968

International Agency for Res

World Health Organization

WHO requirements for screening:

1. The disease sought is an important public health problem
2. The disease has a recognisable latent, preclinical stage
3. There is understanding of the natural history: from latent to clinical disease
4. There is a valid screening test
5. The screening test is acceptable to the population
6. There is established treatment for preclinical stage
7. Resources for verification of diagnosis in screen positive cases are available
8. Resources for treatment of diagnosed cases are available
9. Realistic costs in relation to other health care needs
10. Screening must be a continuous process

International Agency for Research on Cancer

World Health Organization

Key characteristics of cervical cancer screening programme 1: programme structure

- Catchment area
- Start date of the programme
- Youngest age targeted for screening
- Oldest age targeted for screening
- Recommended interval between negative tests (in years)
- Groups (if any) not eligible to participate in screening (e.g. hysterectomised)
- Screening test

International Agency for Research on Cancer
World Health Organization

Key characteristiscs 2: does the programme invite

- All women in the eligible target population, regardless of Pap test history?
- All women in the eligible target population, except those who had a recent Pap test (within the past 6 months or 1 year)?
- Only the women in the eligible target population who did not receive a Pap test within the recommended screening interval (3 or 5 years)?
- Other, specify:
- No invitations are issued?

International Agency for Research on Cancer
World Health Organization

Key characteristics 3: does the invitation include

- A pre-fixed, modifiable appointment?
- An invitation to get in touch to arrange an appointment?
- Other, specify:

International Agency for Research on Cancer
World Health Organization

Key characteristics 4: Are noncompliers reminded?

- All women?
- Some women? Specify: e.g. referral for colposcopy after repeated test? After HPV triage?
- None

International Agency for Research on Cancer
World Health Organization

Key characteristics 5: diagnostic protocols

- Cytology results for which repeat cytology is recommended
- Cytology results for which referral for colposcopy is recommended

International Agency for Research on Cancer
World Health Organization

Evidence of effectiveness

- Should be based on reduction of cervical cancer morbidity and mortality
- Reduction in incidence of grade 3 cervical intraepithelial neoplasia (CIN3), is a surrogate indicator of effectiveness.

International Agency for Research on Cancer
World Health Organization

Ranking of indicators for effectiveness

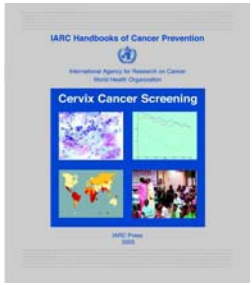
1. Reduction of mortality
2. Reduction of morbidity (QALY)
3. Reduction of incidence
4. Reduction of incidence of CIN3+
5. Increased detection rate of CIN2+ or CIN3+
6. Increased test positivity with increased or similar positive predictive value

International Agency for Research on Cancer
World Health Organization

IARC HANDBOOK OF CANCER PREVENTION

Cervix Cancer Screening

Volume 10, Febr. 2005



35-64 yrs: ≥80% in participants

International Agency for Research on Cancer
World Health Organization

- European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis. Fourth edition. http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication-Start?PublicationKey=ND7306954

- European Guidelines for Quality Assurance in Cervical Cancer Screening. Second edition http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication-Start?PublicationKey=ND7007117

International Agency for Research on Cancer
World Health Organization

Дзякуй за вашу ўвагу !

International Agency for Research on Cancer
World Health Organization

EU Cancer Screening QA Guidelines Underlying Concepts

- Screening as a public health endeavour
- Overriding aim of minimising harm and maximising benefit
- Evidence-based recommendations for screening methods and quality assurance
- Adequate, unbiased information to allow informed choice as to whether to attend
- Comprehensive, **multidisciplinary** process of screening
- Standards of performance and procedures of best practice
- **Continuous quality improvement**
- Population-based organisation, monitoring and evaluation

International Agency for Research on Cancer
World Health Organization

L 327/34 EN Official Journal of the European Union 16.12.2003

COUNCIL RECOMMENDATION
of 2 December 2003
on cancer screening

(2003/878/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4), second subparagraph, thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Whereas:

(1) Article 152 of the Treaty provides that Community action is to complement national policies and be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

(2) Further development of cancer screening programmes should be implemented in accordance with national law and national and regional responsibilities for the organisation and delivery of health services and medical care.

(3) Cancer is a major disease and cause of death throughout Europe, including the future Member States. An estimated number of 1 580 096 new cancer cases, excluding non-melanoma skin cancer, occurred in the European Union in 1998. Of these, 1,4 % were cervical cancers, 13 % breast cancers, 14 % colorectal cancers and 9 % prostate cancers. Cervical and breast cancer constituted 3 % and 29 %, respectively, of new cancers in women. Prostate cancer constituted 17 % of new cancers in men.

(4) Principles for screening as a tool for the prevention of chronic non-communicable diseases were published by the World Health Organisation in 1968 and by the Council of Europe in 1994. These two documents form, together with the current best practice in each of the cancer screening fields, the basis for the present recommendations.

(5) Additionally, these recommendations are based on the 'Recommendations on cancer screening' of the Advisory Committee on Cancer Prevention together with the experience gathered under the different actions sustained under the Europe against Cancer programme where European collaboration has helped, for example, high quality cancer screening programmes to provide efficient European guidelines of best practice and to protect the population from poor quality screening.

(6) Important factors which have to be assessed before a population-wide implementation is decided upon include, *inter alia*, the frequency and interval of the application of the screening test as well as other national or regional epidemiological specificities.

(7) Screening allows detection of cancers at an early stage of invasiveness or possibly even before they become invasive. Some lesions can then be treated more effectively and the patients can expect to be cured. The main indicator for the effectiveness of screening is a decrease in disease-specific mortality. As in the case of cervical cancer, cancer precursors are detected, a reduction in cervical cancer incidence can be considered a very helpful indicator.

(8) Evidence exists concerning the efficacy of screening for breast cancer and colorectal cancer, derived from randomised trials, and for cervical cancer, derived from observational studies.

(9) Screening is, however, the testing for diseases of people for which no symptoms have been detected. In addition to its beneficial effect on the disease-specific mortality, screening can also have negative side effects for the screened population. Healthcare providers should be aware of all the potential benefits and risks of screening for a given cancer site before embarking on new population-based cancer screening programmes. Furthermore, for the informed public of today, these benefits and risks need to be presented in a way that allows individual citizens to decide on participation in the screening programmes for themselves.

(10) Ethical, legal, social, medical, organisational and economic aspects have to be considered before decisions can be made on the implementation of cancer screening programmes.

(11) Due account should be taken of specific needs of persons who may be at higher cancer risk for particular reasons (e.g. biological, genetic, lifestyle and environmental, including occupational).

(12) The public health benefits and cost efficiency of a screening programme are achieved if the programme is implemented systematically, covering the whole target population and following best-practice guidelines.

(13) The cost-effectiveness of cancer screening depends on several factors such as epidemiology, and healthcare organisation and delivery.

(14) Systematic implementation requires an organisation with a call/recall system and with quality assurance at all levels, and an effective and appropriate diagnostic, treatment and after-care service following evidence-based guidelines.

(15) Centralised data systems, including a list of all categories of persons to be targeted by the screening programme and data on all screening tests, assessment and final diagnoses, are needed to run organised screening programmes.

(16) All procedures for collecting, storing, transmitting and analysing data in the medical registers involved must be in full compliance with the level of protection referred to in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ([1]), as well as in full compliance with the relevant provisions of Member States on the management and processing of health data in accordance with Article 8 of the Directive.

(17) Quality screening includes analysis of the process and outcome of the screening and rapid reporting of these results to the population and screening providers.

(18) This analysis is facilitated if the screening database can be linked to cancer registries and mortality databases.

(19) Adequate training of personnel is a prerequisite for high quality screening.

(20) Specific performance indicators have been established for cancer screening tests. These should be monitored regularly.

([1]) OJ L 281, 23.11.1995, p. 31.

(21) Adequate human and financial resources should be available in order to assure the appropriate organisation and quality control in all the Member States.

(22) Action should be taken to ensure equal access to screening taking due account of the possible need to target particular socioeconomic groups.

(23) It is an ethical, legal and social prerequisite that cancer screening should only be offered to fully informed people with no symptoms if the screening is proved to decrease disease-specific mortality, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable.

(24) The screening methods which presently meet these strict prerequisites are listed in the Annex.

(25) No screening test other than those listed in the Annex is scientifically justified to be offered to people with no symptoms in an organised population-based programme before it has been shown in randomised controlled trials to decrease disease-specific mortality in particular.

(26) The screening tests listed in the Annex can only be offered on a population basis in organised screening programmes with quality assurance at all levels, if good information about benefits and risks, adequate resources for screening, follow-up with complementary diagnostic procedures and, if necessary, treatment of those with a positive screening test are available.

(27) The introduction of the recommended screening tests in the Annex, which have demonstrated their efficacy, should be seriously considered, the decision being based on available professional expertise and priority-setting for healthcare resources in each Member State.

(28) Once there is evidence that a new screening test is effective, evaluation of modified tests may be possible using other epidemiologically validated surrogate endpoints if the predictive value of these endpoints is established.

(29) Screening methodologies are subject to ongoing development. The application of recommended screening methodologies should therefore be accompanied by simultaneous assessments of the quality, applicability and cost-effectiveness of new methods if available epidemiological data justify this. In fact, the ongoing work may lead to new methods, which could ultimately replace or complement the tests listed in the Annex or be applicable to other types of cancer,

HEREBY RECOMMENDS THAT MEMBER STATES:

1. Implementation of cancer screening programmes

(a) offer evidence-based cancer screening through a systematic population-based approach with quality assurance at all appropriate levels. The tests which should be considered in this context are listed in the Annex;

(b) implement screening programmes in accordance with European guidelines on best practice where they exist and facilitate the further development of best practice for high quality cancer screening programmes on a national and, where appropriate, regional level;

(c) ensure that the people participating in a screening programme are fully informed about the benefits and risks;

(d) ensure that adequate complementary diagnostic procedures, treatment, psychological support and after-care following evidence-based guidelines of those with a positive screening test are provided for;

(e) make available human and financial resources in order to assure appropriate organisation and quality control;

(f) assess and take decisions on the implementation of a cancer screening programme nationally or regionally depending on the disease burden and the healthcare resources available, the side effects and cost effects of cancer screening, and experience from scientific trials and pilot projects;

(g) set up a systematic call/recall system and quality assurance at all appropriate levels, together with an effective and appropriate diagnostic and treatment and after-care service following evidence-based guidelines;

(h) ensure that due regard is paid to data protection legislation, particularly as it applies to personal health data, prior to implementing cancer screening programmes.

2. Registration and management of screening data

(a) make available centralised data systems needed to run organised screening programmes;

(b) ensure by appropriate means that all persons targeted by the screening programme are invited, by means of a call/recall system, to take part in the programme;

(c) collect, manage and evaluate data on all screening tests, assessment and final diagnoses;

(d) collect, manage and evaluate the data in full accordance with relevant legislation on personal data protection.

3. Monitoring

(a) regularly monitor the process and outcome of organised screening and report these results quickly to the public and the personnel providing the screening;

(b) adhere to the standards defined by the European Network of Cancer Registries in establishing and maintaining the screening databases in full accordance with relevant legislation on personal data protection;

(c) monitor the screening programmes at adequate intervals.

4. Training

adequately train personnel at all levels to ensure that they are able to deliver high quality screening.

5. Compliance

(a) seek a high level of compliance, based on fully informed consent, when organised screening is offered;

(b) take action to ensure equal access to screening taking due account of the possible need to target particular socioeconomic groups.

6. Introduction of novel screening tests taking into account international research results

(a) implement new cancer screening tests in routine healthcare only after they have been evaluated in randomised controlled trials;

(b) run trials, in addition to those on screening-specific parameters and mortality, on subsequent treatment procedures, clinical outcome, side effects, morbidity and quality of life;

(c) assess level of evidence concerning effects of new methods by pooling of trial results from representative settings;

(d) consider the introduction into routine healthcare of potentially promising new screening tests, which are currently being evaluated in randomised controlled trials, once the evidence is conclusive and other relevant aspects, such as cost-effectiveness in the different healthcare systems, have been taken into account;

(e) consider the introduction into routine healthcare of potentially promising new modifications of established screening tests, once the effectiveness of the modification has been successfully evaluated, possibly using other epidemiologically validated surrogate endpoints.

7. Implementation report and follow-up

   report to the Commission on the implementation of this Recommendation within three years of its adoption and subsequently at the request of the Commission with a view to contributing to the follow-up of this Recommendation at Community level.

HEREBY INVITES THE COMMISSION:

1. To report on the implementation of cancer screening programmes, on the basis of the information provided by Member States, not later than the end of the fourth year after the date of adoption of this Recommendation, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action.
2. To encourage cooperation between Member States in research and exchange of best practices as regards cancer screening with a view to developing and evaluating new screening methods or improving existing ones.
3. To support European research on cancer screening including the development of new guidelines and the updating of existing guidelines for cancer screening.

Done at Brussels, 2 December 2003.

For the Council

The President

R. MARONI

ANNEX

SCREENING TESTS WHICH FULFIL THE REQUIREMENTS OF THE RECOMMENDATION (*):

— pap smear screening for cervical cancer precursors starting not before the age of 20 and not later than the age of 30;

— mammography screening for breast cancer in women aged 50 to 69 in accordance with European guidelines on quality assurance in mammography;

— faecal occult blood screening for colorectal cancer in men and women aged 50 to 74.

(*) The indicated age ranges are to be understood as maximum ranges; subject to national epidemiological evidence and prioritisation, smaller age ranges may be appropriate.